

Exhibit C

Suzanne Parisian, M.D.

Page 1

1 UNITED STATES DISTRICT COURT
 2 SOUTHERN DISTRICT OF WEST VIRGINIA
 3 CHARLESTON DIVISION

4 -----)
 IN RE: ETHICON, INC., PELVIC) Master File No.
 5 REPAIR SYSTEM PRODUCTS) 2:12-MD-02327
 LIABILITY LITIGATION) MDL 2327

6)
) JOSEPH R. GOODWIN
) U.S. DISTRICT JUDGE

7 -----)
 Shirley Freeman, et al.,)

8 Plaintiffs,)

9 vs.) Case No.
 10) 2:12-cv-00490

11 ETHICON, INC., et al.,)

12 Defendants.)
 13 -----)

14 PROLIFT+M

15 Tuesday, March 8, 2016

16 - - -

17 Deposition of SUZANNE PARISIAN, M.D.,
 18 held at Marriott Tempe at the Buttes, 2000
 West Westcourt Way, Tempe, Arizona,
 19 commencing at 9:00 a.m., on the above date,
 before Alisa Smith, Arizona Certified Court
 Reporter.

20 - - -
 21

22 GOLKOW TECHNOLOGIES, INC.
 23 877.370.3377 ph | 917.591.5672 fax
 24 deps@golkow.com
 25

Suzanne Parisian, M.D.

Page 2			Page 4		
1	APPEARANCES:		1	EXHIBITS MARKED	
2			2		
3	WAGSTAFF & CARTMELL, LLP		3	EXHIBIT DESCRIPTION PAGE	
4	BY: NATE JONES, ESQUIRE		4	10 Red folder containing Dr. Parisian's	16
5	4740 Grand Avenue, Suite 300		5	file	
6	Kansas City, Missouri 64112		6	11 Document with handwritten notes RE:	37
7	816.701.1100		7	Ethicon	
8	njones@wcllp.com		8	12 Normal Pelvic Anatomy Diagram	63
9	Representing Plaintiffs		9	13 Pelvic floor diagrams	64
10			10	14 Sources of Risk Information Piechart	69
11	AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC		11	15 Gynecare Prolift Surgeon's Resource	89
12	BY: BRYAN F. AYLSTOCK, ESQUIRE		12	Monograph	
13	17 East Main Street, Suite 200		13	16 Medical Literature re Prolift+M	93
14	Pensacola, Florida 32502		14	17 Gynecare Prolift+M labeling	115
15	850.202.1010		15	18 Gynecare Prolift+M and Prosima patient	159
16	baylstock@awkolaw.com		16	brochure	
17	Representing Plaintiffs		17	19 Composite exhibit containing medical	167
18			18	literature	
19			19		
20			20		
21			21		
22			22		
23			23		
24			24		
25			25		

Page 3			Page 5		
1	I N D E X		1	SUZANNE PARISIAN, M.D.,	
2	WITNESS PAGE		2	the witness herein, having been first duly sworn by	
3	SUZANNE PARISIAN, M.D.		3	the Certified Court Reporter, was examined and	
4	Direct Examination by Mr. Gage	5	4	testified as follows:	
5			5	DIRECT EXAMINATION	
6	* * * * *		6	BY MR. GAGE:	
7	EXHIBITS MARKED		7	Q. Good morning, Dr. Parisian.	
8			8	A. Good morning.	
9	EXHIBIT DESCRIPTION PAGE		9	Q. My name is William Gage. I'm with Butler	
10	1 Notice to Take Deposition of Suzanne	6	10	Snow Law Firm. I'll be taking your deposition	
11	Parisian		11	today.	
12	2 Dr. Parisian's Expert Report	6	12	Could you state your name, please?	
13	3 List of Documents Provided or	6	13	A. My name is Dr. Suzanne Parisian.	
14	Identified for Review in the above		14	Q. And your current address?	
15	Referenced Lawsuit		15	A. 7117 North Third Street, Phoenix, Arizona.	
16	4 Suzanne Parisian, M.D.'s CV	6	16	Q. And, Dr. Parisian, as we discussed before	
17	5 Legal Testimony History, Suzanne	6	17	the deposition, we only have three hours under	
18	Parisian, M.D.		18	the -- either the court order and/or agreement of	
19	6 Composite Exhibit re Surgical Mesh	6	19	the parties, so there may be places where -- and	
20	Action Team		20	I'll apologize in advance -- where if, you know,	
21	7 Reclassification of Urogynecologic	10	21	counsel will permit, I may sometimes withdraw	
22	Surgical Mesh Instrumentation, FDA		22	questions if it looks that your answer is going to	
23	Questions		23	be too long or too convoluted, because I would	
24	8 Black binder notebook	15	24	rather move to another subject.	
25	9 Black binder notebook	15	25	So I apologize in advance for perhaps at	

2 (Pages 2 to 5)

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<p style="text-align: right;">Page 6</p> <p>1 times being curt, but it's because of the short time 2 limit, so -- and I know counsel may not always agree 3 with me, but we'll manage and try to work the best 4 that we can. 5 A. Yes, sir. 6 (Whereupon, Exhibit Nos. 1 through 6 7 were marked for identification.) 8 BY MR. GAGE: 9 Q. We've premarked some exhibits. 10 Exhibit 1 to the deposition is the 11 deposition notice. Exhibit 2 to the deposition is 12 Dr. Parisian's report. 13 Is that correct, Dr. Parisian? 14 A. Yes, sir. 15 Q. Exhibit 3 is a document entitled "List of 16 documents provided or identified for review in the 17 above-referenced lawsuit." 18 And, Dr. Parisian, you're familiar with that 19 document? 20 A. Yes, sir. 21 Q. Document 4 is Dr. Parisian's current CV. 22 And, Doctor, you agree with that? 23 A. Yes, sir. 24 Q. Exhibit 5 is a list of Dr. Parisian's court 25 testimony from January 2011 to January 2016, which</p>	<p style="text-align: right;">Page 8</p> <p>1 working copy. And so when I finish it, I send it to 2 them. 3 Q. All right. And when you sent it to them, 4 did you send it to them signed, or did you send it 5 to them unsigned and then request feedback or 6 comment? 7 A. Well, I have to -- to sign it, I have to 8 scan my signature, so they're all unsigned, and then 9 I have to scan the signature and send it to them. 10 Q. All right. So when you typed your report 11 and sent it to plaintiffs' counsel, the version that 12 we are working with today is the same version that 13 you would have sent to plaintiffs' counsel? 14 A. Yes, sir. 15 Q. Okay. Are there any other documents apart 16 from your report that -- that you created as part of 17 your work in this case? 18 A. No. 19 Q. No spreadsheets, databases, or other data 20 compilations? 21 A. That's correct. 22 Q. And are all of the opinions you tend -- you 23 intend to offer in this case contained within the 24 confines of your expert report? 25 A. Well, it depends what you ask me. I've</p>
<p style="text-align: right;">Page 7</p> <p>1 you, Dr. Parisian, provided us; correct? 2 A. Yes, sir. 3 Q. And then Exhibit 6 is a collection of 4 documents. It's a composite exhibit. It contains 5 probably a quarter of an inch stack of documents 6 that counsel represented before the deposition 7 started are documents that were obtained, presumably 8 by plaintiffs, from FDA through an open records 9 request, that relate to various issues at the FDA 10 with regard to pelvic mesh. 11 And, Dr. Parisian, I assume you've reviewed 12 these as well? 13 A. Yes, sir. 14 Q. All right. And that collection of documents 15 is marked as Exhibit 6. 16 All right. Dr. Parisian, with respect to -- 17 with respect to your report, who typed it? 18 A. Me. All the typos are mine. 19 Q. Okay. Did you send a copy to plaintiffs' 20 counsel for review before you finalized it? 21 A. No. 22 Q. You just wrote it? 23 A. Yes, sir. 24 Q. Okay. Is this just one draft? 25 A. Yes, sir. It's not really a draft. It's a</p>	<p style="text-align: right;">Page 9</p> <p>1 tried to summarize them. If there's -- more 2 documents come up, then -- like this document that 3 just came, you know, that's not in my report. So 4 I -- at the time I wrote the report, I tried to 5 capture the information. 6 Q. All right. And what you're referring to 7 when you talk about "the document" is Exhibit 6; 8 correct? 9 A. Yes, sir. 10 Q. So I understand that, you know, you've given 11 us an expert report that's over 100 pages in length, 12 and I may ask you about certain portions of that 13 today, and you may give me additional information or 14 opinions. 15 Presumably, those will all be subparts, if 16 you will, of what's contained in the document? 17 A. Hopefully, yes, sir. That's what this is 18 for; right? 19 Q. Right. 20 And then you've got Exhibit 6, which is 21 really kind of new and separate and apart from the 22 actual report itself; correct? 23 A. True. I mean, I knew that there was a 24 working group. I just had never seen the documents 25 from the working group before.</p>

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<p style="text-align: right;">Page 10</p> <p>1 Q. All right. And apart from Exhibit 6, you're</p> <p>2 not aware of any other document or database or</p> <p>3 notation of ideas or concepts that you have created</p> <p>4 or that you would use to provide opinions that are</p> <p>5 not already contained within your report?</p> <p>6 A. That would be -- there actually has been a</p> <p>7 release by FDA, the reclassification of instruments,</p> <p>8 and that was just February 26, so there are those</p> <p>9 documents.</p> <p>10 Q. All right. So, Dr. Parisian, you just</p> <p>11 handed me a collection of documents about maybe a</p> <p>12 quarter of an inch --</p> <p>13 A. Yes.</p> <p>14 Q. -- maybe an eighth of an inch to a quarter</p> <p>15 of an inch high. I'm going to mark those</p> <p>16 collectively as Exhibit 7.</p> <p>17 A. Right. And those are from the FDA's Web</p> <p>18 site.</p> <p>19 (Whereupon, Exhibit No. 7 was marked</p> <p>20 for identification.)</p> <p>21 BY MR. GAGE:</p> <p>22 Q. All right. And just looking over those, the</p> <p>23 document -- first document is entitled,</p> <p>24 "Reclassification of Urogynecologic Surgical Mesh</p> <p>25 Instrumentation, FDA Questions," dated</p>	<p style="text-align: right;">Page 12</p> <p>1 which is your list of documents provided or</p> <p>2 identified for review in the above-referenced</p> <p>3 lawsuit --</p> <p>4 A. Yes, sir.</p> <p>5 Q. -- do you see that? --</p> <p>6 A. Yes, sir.</p> <p>7 Q. -- who typed this document?</p> <p>8 A. I didn't type it.</p> <p>9 Q. Do you know who typed it?</p> <p>10 A. No.</p> <p>11 Q. Do you know how you came into possession of</p> <p>12 it?</p> <p>13 A. No. I knew that -- no, I don't.</p> <p>14 Q. Okay. Do you understand this document to</p> <p>15 be -- and I'm speculating here, but I'll throw it</p> <p>16 out and see what you know.</p> <p>17 Do you understand this document to have been</p> <p>18 prepared by plaintiffs' counsel in this case?</p> <p>19 A. Yes, sir.</p> <p>20 Q. Okay. And this -- have you reviewed this</p> <p>21 document?</p> <p>22 A. I haven't reviewed it, no, sir.</p> <p>23 Q. So you don't know whether this document,</p> <p>24 Exhibit 3, contains a list of everything that has</p> <p>25 been provided to you?</p>
<p style="text-align: right;">Page 11</p> <p>1 February 26, 2016; correct?</p> <p>2 A. Yes, sir.</p> <p>3 Q. All right. And then behind that appears to</p> <p>4 be -- well, there is a document entitled,</p> <p>5 "Reclassification of Urogynecologic Surgical Mesh</p> <p>6 Instrumentation," dated February 26, 2016; correct?</p> <p>7 A. Yes, sir.</p> <p>8 And I mentioned that the FDA was going to</p> <p>9 reclassify them in my report --</p> <p>10 Q. Yes.</p> <p>11 A. -- so this has just subsequently come out on</p> <p>12 the FDA's Web site.</p> <p>13 Q. All right. So we'll -- we will talk about</p> <p>14 this document, which I have now marked as collective</p> <p>15 Exhibit 7.</p> <p>16 Are there any other additional documents or</p> <p>17 data summaries, compilations of data, of any shape,</p> <p>18 form, or character other than what we've already</p> <p>19 discussed?</p> <p>20 A. I don't believe so.</p> <p>21 Q. Okay. Do you have any plans on</p> <p>22 supplementing any of your opinions with regard to</p> <p>23 Prolift+M?</p> <p>24 A. Not that I'm aware of.</p> <p>25 Q. Dr. Parisian, with regard to Exhibit 3,</p>	<p style="text-align: right;">Page 13</p> <p>1 MR. JONES: Objection.</p> <p>2 THE WITNESS: I don't know that it</p> <p>3 does.</p> <p>4 I mean, in terms of what has been</p> <p>5 provided, I know that there was -- the people</p> <p>6 providing me were keeping track of it, and then I</p> <p>7 cite some different things in my report, and so</p> <p>8 they're trying to put that in.</p> <p>9 I didn't type the list. I don't have</p> <p>10 any reason to think that it wouldn't contain it, and</p> <p>11 that's why I brought the documents that I thought</p> <p>12 may be new documents and not on the list.</p> <p>13 BY MR. GAGE:</p> <p>14 Q. Do you have a separate list of documents</p> <p>15 that have been provided to you or which you have</p> <p>16 reviewed in connection with your expert report?</p> <p>17 A. No.</p> <p>18 Q. How did you physically receive documents?</p> <p>19 A. I received them in folders, these black</p> <p>20 binders which I brought today, and so that's how I</p> <p>21 received them.</p> <p>22 Q. Okay. So I'm going to just stand up and</p> <p>23 kind of go walk around on the other side of the</p> <p>24 table to just take a look at the black folders.</p> <p>25 So what you have -- what you've brought with</p>

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<p style="text-align: right;">Page 14</p> <p>1 you to the deposition today are three large black 2 binders that fit into one box, and they have -- one 3 of them is TVT-Secur, so we'll save that one for the 4 next deposition. 5 That leaves two other binders, and one of 6 those two -- Dr. Parisian, this one at least, when I 7 pick up the first document, appears to relate to 8 Prolift+M. Is that correct? 9 A. Yes, sir. 10 Q. So is it fair to say, is the other one 11 Prolift+M or is it Secur? 12 A. It's 522 -- it's the 522 documents. 13 Q. Okay. 14 A. And I think -- I know TVT Secur had been in 15 the Garcia deposition, that black binder. 16 Q. Yes. 17 A. I haven't touched it since then, and so that 18 was there at that deposition. 19 Q. Okay. Well, I'll tell you what. So that I 20 don't forget it, I'm going to put the TVT Secur 21 notebook on top of my TVT -- I'm going to give it 22 back to you, but I'm going to put it over here so 23 that when we take this deposition, hopefully I'll 24 remember to ask you about it. If I don't, maybe you 25 can remind me.</p>	<p style="text-align: right;">Page 16</p> <p>1 way we can. 2 MR. GAGE: Yeah, We'll figure out a 3 way, and I will definitely want to get a copy of 4 this, but I know we don't really have that -- I 5 don't think we have that ability to do it today. 6 MR. JONES: I think we can work 7 together to find a solution. 8 MR. GAGE: But, Counsel, can I ask that 9 I have a copy of all the handwritten notes and the 10 stickies? 11 MR. JONES: You will get that binder, 12 absolutely. 13 MR. GAGE: Perfect. Thank you. 14 And the same for Exhibit 9 as well and 15 the TVT-Secur. Okay. Thank you. 16 THE WITNESS: And then these are 17 documents that I went and pulled, too, that relate 18 to the Prolift+M, so some of those are mine. That's 19 my file, so you have my file. 20 (Whereupon, Exhibit No. 10 was marked 21 for identification.) 22 BY MR. GAGE: 23 Q. All right. So that -- so Dr. Parisian's 24 handed me a folder, a red folder, that's probably 25 two inches thick --</p>
<p style="text-align: right;">Page 15</p> <p>1 A. Okay. 2 Q. All right. So with regard to Prolift+M, we 3 have two notebooks here. One you're saying relates 4 primarily to the 522 issues? 5 A. Yes, sir. 6 Q. And the second of which is just really kind 7 of your general Prolift+M documents, and I also see 8 that you've got some notes in here too. Is that 9 correct? 10 A. Yes, sir. 11 (Whereupon, Exhibit Nos. 8 and 9 were 12 marked for identification.) 13 BY MR. GAGE: 14 Q. All right. So why don't we mark as 15 Exhibit 8 this notebook that you've given me that 16 contains a lot of handwriting, a lot of sticky 17 notes, and then a lot of photocopied documents. 18 And I'll ask you, Doctor -- and then we'll 19 mark as Exhibit 9 the notebook that you told me 20 relates primarily to the 522 orders. 21 And Nate and Bryan and I will figure out 22 later how we photocopy this because I hate to create 23 a gigantic depo with a gigantic amount of exhibits, 24 but we'll figure out -- 25 MR. JONES: The best way, the easiest</p>	<p style="text-align: right;">Page 17</p> <p>1 A. Yeah. I guess so, yeah. 2 Q. -- about two inches thick of documents that 3 Dr. Parisian -- Dr. Parisian, did you identify this 4 as your file? 5 A. Yeah, that's my file. Not everything fit in 6 the notebook. 7 Q. Okay. So these would just be documents much 8 like those found in Exhibit 8, but they just 9 wouldn't fit inside of that notebook -- 10 A. Correct. 11 Q. -- that we've marked as -- 12 A. And they weren't sent to me. I went and got 13 them. 14 Q. Okay. That's -- that's important. 15 A. Right. 16 They're not that -- they're not that 17 exciting of documents, but I just wanted you to have 18 the whole thing. 19 Q. Was everything in Exhibit 8 provided to you 20 by plaintiffs' counsel? 21 A. Yes, sir. 22 Q. Was everything in Exhibit 9 provided to you 23 by plaintiffs' counsel? 24 A. Yes, sir. 25 Q. And everything in Exhibit 10 were documents</p>

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<p style="text-align: right;">Page 18</p> <p>1 that you got on your own?</p> <p>2 A. Yeah. Miscellaneous documents, yes, sir.</p> <p>3 Q. Okay. And then the documents that we talked</p> <p>4 about that were part of Exhibit 6 from FDA, those</p> <p>5 were provided to you by plaintiffs' counsel;</p> <p>6 correct?</p> <p>7 A. Yes, sir.</p> <p>8 Q. What about Exhibit 7, the reclassification</p> <p>9 documents?</p> <p>10 A. No. I went and got those.</p> <p>11 Q. Okay. So Exhibit 7 and Exhibit 10 are</p> <p>12 the -- would it be correct to say that what is found</p> <p>13 in Exhibit 7 and Exhibit 10 are the only documents</p> <p>14 that you have gathered on your own accord in</p> <p>15 connection with your opinions on Prolift+M?</p> <p>16 MR. JONES: Objection.</p> <p>17 THE WITNESS: I believe that's correct,</p> <p>18 because I think -- I mean, obviously, I referenced</p> <p>19 the guidance documents, like the surgical mesh</p> <p>20 guidance and the -- and I believe they're in those</p> <p>21 black folders.</p> <p>22 But I would have gotten my own 510(k)s,</p> <p>23 and -- and some of them are in there, but some of</p> <p>24 those guidance documents I think are -- I just</p> <p>25 didn't want to be duplicative.</p>	<p style="text-align: right;">Page 20</p> <p>1 there are some things that I got from -- from my</p> <p>2 search of the national medical library, blood work,</p> <p>3 abstracts, and so those are in there.</p> <p>4 So see -- there they are, the abstracts and</p> <p>5 stuff, because some of them are in French -- so you</p> <p>6 would have it all.</p> <p>7 Q. Okay. As I look through -- as I'm looking</p> <p>8 through the documents in Exhibit 10, I see the</p> <p>9 deposition of Marty Weisberg from November 2015, I</p> <p>10 see Prolift+M FDA 510(k) timeline, 522 Order and</p> <p>11 re-commercialization. I see some information about</p> <p>12 ENDOLOOP?</p> <p>13 A. Right, because I talk about ENDOLOOP in my</p> <p>14 report, so those are the documents I pulled.</p> <p>15 Q. Okay. I see some stuff about ARTISYN. I</p> <p>16 see some information about -- some information you</p> <p>17 pulled back on the MAUDE database. Is that correct?</p> <p>18 A. Yes, sir.</p> <p>19 Q. And then I see a document called Summary of</p> <p>20 Care for Carolyn Moorehead?</p> <p>21 A. Right.</p> <p>22 Q. What is that?</p> <p>23 A. That was how I originally got this. It was</p> <p>24 going to be Ms. Moorehead's case, Prolift+M. I</p> <p>25 think they -- I don't know -- I don't know what</p>
<p style="text-align: right;">Page 19</p> <p>1 BY MR. GAGE:</p> <p>2 Q. Okay. So what about medical literature? If</p> <p>3 I wanted to know every piece of medical literature</p> <p>4 that you reviewed in connection with your opinions</p> <p>5 on Prolift+M, where would I go to find that?</p> <p>6 A. Some of it would be in the black folders. I</p> <p>7 don't have a file for medical literature for</p> <p>8 Prolift+M. So a lot of it would have come from the</p> <p>9 folders -- would have been in the black documents</p> <p>10 that were given to me.</p> <p>11 Q. And if counsel -- if the list that's marked</p> <p>12 as Exhibit 3, what we sometimes call the reliance</p> <p>13 list, is accurate, it would presumably contain every</p> <p>14 document that is in Exhibit 8?</p> <p>15 A. It should, yeah. I would expect it to.</p> <p>16 Q. Okay. So the universe of medical literature</p> <p>17 that you reviewed would either be in Exhibit 3, or</p> <p>18 if maybe counsel made a mistake and didn't type it</p> <p>19 up, it would be in Exhibit 8?</p> <p>20 A. Yes.</p> <p>21 Q. You do not have a separate stack, pile, or</p> <p>22 collection of medical literature that you reviewed</p> <p>23 for the Prolift+M case that is apart from what</p> <p>24 you've handed me today?</p> <p>25 A. No. And if you look in the red folder,</p>	<p style="text-align: right;">Page 21</p> <p>1 happened to Ms. Moorehead, but that's what I</p> <p>2 received.</p> <p>3 Q. All right.</p> <p>4 MR. GAGE: I would -- I would ask</p> <p>5 counsel, plaintiffs' counsel --</p> <p>6 MR. JONES: Just for the record, I</p> <p>7 think that's related to her prior involvement in the</p> <p>8 TVT-Secur case, and so I think she's trying to be --</p> <p>9 over-sharing perhaps in giving her complete file and</p> <p>10 anything -- so if that's part of her complete file,</p> <p>11 and so we'll take that out and make sure that's not</p> <p>12 in the final exhibit.</p> <p>13 MR. GAGE: I think, unless you guys</p> <p>14 disagree, the document that I am looking at is</p> <p>15 purely -- it's about a seven- or eight-page</p> <p>16 document. It appears to be --</p> <p>17 THE WITNESS: Just medical history.</p> <p>18 MR. GAGE: -- exclusively related to</p> <p>19 one plaintiff, and it goes into quite a good bit of</p> <p>20 detail about her individual health.</p> <p>21 MR. JONES: Absolutely.</p> <p>22 MR. GAGE: What I would recommend is --</p> <p>23 I would like a copy of it, but I do not believe it</p> <p>24 should be marked as an exhibit unless you're</p> <p>25 prepared to redact almost everything out of it,</p>

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<p style="text-align: right;">Page 22</p> <p>1 because I don't think that this needs to be 2 generally circulated with her deposition transcript. 3 MR. JONES: Correct. 4 MR. GAGE: We agree to that? 5 MR. JONES: And I think what might be 6 the best approach is for me to go through that 7 particular exhibit prior to it being formally 8 marked, and like you said, give it a careful read 9 and make sure there's no information in there that 10 shouldn't be in there. 11 MR. GAGE: I don't -- you know, if 12 somebody wants a copy of the deposition of 13 Dr. Parisian that we've taken, I would like to be 14 able to give it to them without worrying about 15 somebody's very specific -- 16 THE WITNESS: Should I give it to him 17 and have him look at it? 18 MR. GAGE: I mean, I would like a copy 19 of it, and I think as counsel I can look at it, but 20 I don't want it to be part of the record that gets 21 moved around. 22 BY MR. GAGE: 23 Q. All right. All right. 24 So, Dr. Parisian, let me ask you this about 25 your reliance list.</p>	<p style="text-align: right;">Page 24</p> <p>1 plaintiffs' counsel; correct? 2 A. Right. 3 Q. Apart from Exhibit 6, did you ever go 4 through your documentation that was provided to you 5 by plaintiffs' counsel and ask them to send you 6 anything else to review in connection with your 7 Prolift+M opinions? 8 A. I don't think so. 9 Q. Okay. Exhibit 4 is your CV, and I assume it 10 is current? 11 A. Yeah. Yes, it is. 12 Q. Exhibit 5 is your list of court testimony 13 from January 2011 to January 2016. 14 I assume the definition of court testimony, 15 this is every place that you've ever been deposed or 16 testified live at trial during those -- during that 17 time period. Is that correct? 18 A. Yes, sir. 19 Q. And is that -- is this list current and 20 accurate and correct? 21 A. Yes, sir. 22 Q. Let me ask you this before I forget. You 23 have been asked at prior depositions if you have -- 24 if your testimony has ever been excluded, and I know 25 there have been a couple of occasions that you've</p>
<p style="text-align: right;">Page 23</p> <p>1 A. Um-hmm. 2 Q. You indicated earlier, I believe, that 3 plaintiffs' counsel provided you with some documents 4 to review. Is that correct? 5 A. Yes, sir. 6 Q. Did you ask for any additional documents 7 from plaintiffs' counsel? 8 A. I asked for any FDA-related documents, and 9 that was why they gave me the document that we have 10 now -- is that Exhibit 6 or -- 11 Q. Is it Exhibit 8? 12 A. No. It's the one you just got today. 13 Q. Exhibit 6? 14 A. Yeah, Exhibit 6. And that's how I happened 15 to come upon it, because I said I wanted anything 16 FDA-related, and so they gave me that. 17 Q. All right. So Exhibit 6 was not in the 18 stack of documents that they originally provided 19 you; correct? 20 A. That's correct. 21 Q. And then with respect to the documents that 22 are on your reliance list, do you know who made the 23 determination as to what to send to you? 24 A. No. 25 Q. Presumably, it would have been somebody with</p>	<p style="text-align: right;">Page 25</p> <p>1 indicated. 2 Are you aware of any time in the last two 3 years where your testimony has been excluded for any 4 reason? 5 A. No. 6 Q. Okay. So the instances where your testimony 7 has been excluded, at least to your knowledge, 8 predate the last two years? 9 A. Yes. 10 Q. It would have been -- it would have been 11 sometime earlier than 2014? 12 A. Yes. And by excluded, I'm not saying -- 13 sometimes a judge will say, "You can't talk about 14 this. You can't talk about that," but we're talking 15 about excluded where I didn't go to court and stuff, 16 and I only know of maybe one time. 17 Q. All right. And Exhibit 7, which was the 18 reclassification documents, you pulled those 19 yourself off the FDA Web site. Is that correct? 20 A. Yes, sir. 21 Q. All right. And the original document that 22 you handed me has your highlights on it? 23 A. Yes, sir. 24 MR. GAGE: So, Nate, as we set about 25 the task of photocopying these things, I would ask</p>

7 (Pages 22 to 25)

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<p style="text-align: right;">Page 26</p> <p>1 that the highlighting be --</p> <p>2 MR. JONES: Yeah. You will get them as</p> <p>3 produced.</p> <p>4 MR. GAGE: -- replicated as they're</p> <p>5 produced.</p> <p>6 BY MR. GAGE:</p> <p>7 Q. All right. So, Dr. Parisian, I'm on Exhibit</p> <p>8 No. 8, which is the notebook of documents.</p> <p>9 And I think, if I'm remembering correctly,</p> <p>10 you've testified this is largely a printoff or a</p> <p>11 printout of documents that were provided to you by</p> <p>12 plaintiffs' counsel. Is that correct?</p> <p>13 A. These were the only documents that were</p> <p>14 provided to me.</p> <p>15 Q. Okay. Were they provided to you in the form</p> <p>16 of a notebook, on paper, or were they provided to</p> <p>17 you on a disk or some other electronic means?</p> <p>18 A. In a notebook. You have them as -- that was</p> <p>19 how they were provided.</p> <p>20 Q. Okay. So the actual document, Exhibit 8, or</p> <p>21 the actual Exhibit 8 is the actual notebook that</p> <p>22 plaintiffs' counsel actually provided to you?</p> <p>23 A. Yes, sir.</p> <p>24 Q. Okay. And apart from this -- apart from</p> <p>25 Exhibit 8 and Exhibit 9 -- well, let me -- actually,</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Are you waiting on any information which</p> <p>2 might cause you to alter your opinions in this case?</p> <p>3 A. No, sir.</p> <p>4 Q. Have you -- is there any pending request to</p> <p>5 plaintiffs' counsel for additional documents or</p> <p>6 information that you are waiting on with regard to</p> <p>7 Prolift+M?</p> <p>8 A. No, sir.</p> <p>9 Q. I may have covered this earlier, but I'm not</p> <p>10 sure it's clear in my mind, which means it may not</p> <p>11 be clear in the record.</p> <p>12 With regard to medical literature, I think</p> <p>13 you -- that you have reviewed in connection with</p> <p>14 this case, as I understand, it's come from two</p> <p>15 sources. It's either going to be in one of the</p> <p>16 exhibits that we've already marked that came from</p> <p>17 plaintiffs' counsel, or it's going to be in</p> <p>18 Exhibit 10, which is a collection -- which includes</p> <p>19 some documents that you yourself gathered; correct?</p> <p>20 A. Yes, sir.</p> <p>21 Q. I saw that there were several depositions on</p> <p>22 your reliance list.</p> <p>23 Did you read those?</p> <p>24 A. Yes, sir.</p> <p>25 Q. Did you read all of the documents on your</p>
<p style="text-align: right;">Page 27</p> <p>1 strike that.</p> <p>2 Was Exhibit 9, is it -- was it provided to</p> <p>3 you in this form?</p> <p>4 A. Yes, sir.</p> <p>5 Q. Okay. So when I'm holding Exhibit 9, this</p> <p>6 is the actual notebook that was actually provided to</p> <p>7 you by plaintiffs' counsel?</p> <p>8 A. Yes, sir.</p> <p>9 Q. Okay. And Exhibit 8 contains a good bit of</p> <p>10 handwriting.</p> <p>11 I assume all of the handwriting in this is</p> <p>12 yours?</p> <p>13 A. Yes, sir.</p> <p>14 Q. And I assume all of the stickies are yours?</p> <p>15 A. Yes, sir. And there's no color</p> <p>16 coordination.</p> <p>17 Q. Okay. And the highlighting is all done by</p> <p>18 you?</p> <p>19 A. Yes, sir.</p> <p>20 Q. And this was all done after you had been</p> <p>21 retained and before you wrote your report?</p> <p>22 A. Yes, sir.</p> <p>23 Q. Do you have any plans on doing any</p> <p>24 additional work with respect to Prolift+M?</p> <p>25 A. No, sir.</p>	<p style="text-align: right;">Page 29</p> <p>1 reliance list?</p> <p>2 A. Well, let's -- which ones specifically are</p> <p>3 you asking me of?</p> <p>4 Q. Well, let me ask you this.</p> <p>5 A. I don't remember reading them all. I looked</p> <p>6 at parts of them. I wouldn't say that I've read</p> <p>7 every single word of every one of them.</p> <p>8 Q. Okay. So, for example, when I look through</p> <p>9 Exhibit 8 and Exhibit 9 and Exhibit 10, I don't see</p> <p>10 any deposition transcripts, but I see deposition</p> <p>11 transcripts on your reliance list.</p> <p>12 A. Right.</p> <p>13 Q. Can you tell me where those deposition</p> <p>14 transcripts are and how you received them?</p> <p>15 A. No, because I don't -- I don't have them</p> <p>16 sitting on my computer. If they're not in there, I</p> <p>17 haven't reviewed them.</p> <p>18 Q. Okay. So --</p> <p>19 A. And I don't think I cite most of them in</p> <p>20 terms of my report. The ones that I've reviewed I</p> <p>21 cite in my report. Because I know -- I know who</p> <p>22 some of these people are, but I haven't read them</p> <p>23 all, so I don't know where they are.</p> <p>24 Q. All right. So if there's a -- the only</p> <p>25 depositions that you would have read would be</p>

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<p style="text-align: right;">Page 30</p> <p>1 depositions that you specifically cited to in your 2 report. Is that correct? 3 A. Yes, sir. 4 Q. And if there's a deposition that appears on 5 your reliance list, which is marked as Exhibit 3, 6 that is not cited in your expert report, then it 7 means that you did not read that deposition. Is 8 that correct? 9 A. I haven't read all of those depositions, no, 10 sir. That's correct. I know who some of these 11 people are but did not read all their depositions. 12 Q. Okay. So for the depositions that you did 13 read -- 14 A. Um-hmm. 15 Q. -- where are they physically located? 16 It was my understanding you had given us 17 everything that you physically had in your 18 possession, and I don't see any deposition 19 transcripts. And I'm just wanting to know, where 20 are those transcripts? 21 A. You know, I don't recall. I don't recall. 22 I didn't look at my computer last night to see if 23 there are depositions on that. I can go look and 24 see and update you as to what ones I have. 25 Q. Okay.</p>	<p style="text-align: right;">Page 32</p> <p>1 THE WITNESS: Right. 2 MR. GAGE: -- if you could provide 3 me -- would y'all be willing to give me that one 4 page? 5 MR. JONES: We'll talk about it and see 6 what we can do, but we'll work on that. 7 MR. GAGE: Okay. Because I'm going to 8 need something that has the witness's -- 9 MR. JONES: Correct. 10 THE WITNESS: Right. I can do that. 11 Because I didn't look on my computer last night. 12 That's why I can't answer the question. 13 BY MR. GAGE: 14 Q. That's fine. 15 But I just need -- just for posterity and 16 for the depo, I'll need something -- I'll need a 17 document that you have approved and agreed to -- 18 A. Right. 19 Q. -- with regard to that issue, so I'll make 20 that request -- 21 A. Right. 22 Q. -- and we'll work with Nate to get that. 23 A. So you will know who I've read. 24 Q. Exactly. 25 Have you read any expert reports from any</p>
<p style="text-align: right;">Page 31</p> <p>1 A. But I don't -- I didn't look at it last 2 night to see if there's any depositions on there. 3 Q. All right. So I would ask for you to visit 4 with counsel and to give us -- 5 A. Any depositions that I've been sent? 6 Q. -- any depositions that you've been sent. 7 A. Okay. 8 MR. JONES: And I'll just tell you, I 9 didn't print off the depositions for you. I can go 10 do that if that's what you're wanting me to do, but 11 they're not -- the printed 500-page long depositions 12 are not in those binders. We'd have about 20 13 binders. 14 MR. GAGE: Yeah. I think what I would 15 like to have, if it's okay for you, Nate, and 16 Dr. Parisian, is if you guys could just send me a 17 document that says, "Here are the deposition 18 transcripts that I, Dr. Parisian, reviewed" -- I 19 guess it would fall into two categories: "Here are 20 the transcripts I received and didn't review. Here 21 are the transcripts that I received and did review." 22 THE WITNESS: Okay. 23 MR. GAGE: And then just sign your 24 name, "Before I" -- "Before I signed my Prolift+M 25 report" --</p>	<p style="text-align: right;">Page 33</p> <p>1 expert witness in this litigation? 2 A. I know I've read Dr. Miklos' report, but 3 that's our side, isn't that? 4 Q. Yes. 5 And I believe was that in connection with 6 your TVT-Secur opinions in the Garcia case? 7 A. I think so, yeah. 8 Q. Apart from Dr. Miklos' expert report, have 9 you read any expert reports from anyone else in the 10 mesh litigation? 11 A. I don't think I have. 12 Q. And I'll represent to you, I didn't see any 13 in these documents. But in -- as I ask -- as I just 14 asked for the list of deposition transcripts, if 15 you -- when you go back to your computer, if you see 16 that you have received and didn't review expert 17 reports or if you received and did review expert 18 reports, I would ask that you add that to the list. 19 A. I don't recall reviewing any expert reports 20 for Prolift+M. 21 Q. Have you spoken to anyone who you understand 22 to be an expert in this litigation? 23 A. No. 24 Q. And, Dr. Parisian, as I understand it, you 25 have served as an expert witness for plaintiffs in</p>

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<p style="text-align: right;">Page 34</p> <p>1 mesh cases other than those involving Ethicon or 2 Johnson & Johnson. Is that correct? 3 A. Yes, sir. 4 Q. And is it correct to say that anytime you've 5 either testified live in court or been deposed would 6 be reflected on the list of testimony that you gave 7 us? 8 A. That five -- I did -- I don't think on that 9 list would be the ProtoGen. I did ProtoGen, depos 10 in that. That was a long time ago. 11 Q. But that wouldn't be on the list because the 12 list has a cutoff? 13 A. Right. It's five years. 14 Q. Right. 15 A. And then the other thing would have been I 16 was in a case against Johnson & Johnson with an 17 attorney, Ray Putney, that had a sling that had been 18 placed, and a woman had a bone anchor that was pre 19 all this stuff. It was be- -- and so there was an 20 early case against Johnson & Johnson in Texas -- 21 Q. Do you remember -- 22 A. -- and so those wouldn't be in the two -- in 23 the lists that you have. 24 Q. Do you remember what product was involved in 25 that case?</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. And that was within the last couple years? 2 A. Yes, sir. And that's on my history. 3 Q. All right. And you've never been charged 4 with a crime of any type; correct? 5 A. No, sir. Thank goodness. 6 Q. Who actually retained you for your Prolift+M 7 work? 8 A. Lee Lundquist for Clark, Love & Hutson. 9 Q. Had you ever worked for them before? 10 A. Yes, sir. 11 Q. Can you just give me some details about the 12 nature of the relationship with Clark, Love before 13 you were asked to opine on Prolift+M? 14 A. I had worked with them on -- the Garcia case 15 was with them, and I had worked with them -- many 16 attorneys I work with are part of the MDL, and so 17 they had been -- I originally met them in Paxil when 18 I was involved with Paxil litigation. And then I 19 met them again when I was involved with Trasylol, 20 but -- so the only times I was working for them 21 specifically was for mesh, and that was for Ethicon. 22 Q. How long did you work for them on Paxil? 23 A. Paxil is still going on. 24 Q. Are you still doing work for Clark, Love in 25 Paxil?</p>
<p style="text-align: right;">Page 35</p> <p>1 A. It was -- it was -- well, it was Johnson & 2 Johnson's sling, and it was a bone anchor. I think 3 a Mitek bone anchor, and I think it was a PROLENE 4 sling. 5 And it was being done -- this is before they 6 had clearance for this, and that was in Texas. I 7 know the attorney's name is Ray Putney, and I don't 8 remember what the woman's name was. I think -- 9 Anyway, so -- but Johnson & Johnson had 10 actually been in the OR when she was having all this 11 implanted, some of their executives and stuff. 12 Q. Do you know if this was a TVT or a TVT-O? 13 A. Oh, no, no, no. It was pre -- it was before 14 TVT. So it was actually something that the company 15 was looking at before they did their TVT. 16 Q. So this is something that predates -- an 17 implant that would predate 1998? 18 A. Yeah, yes. 19 Q. All right. 20 A. And so that went to court, and then it 21 settled, and so that's not on that list. 22 Q. All right. Have you ever testified in a 23 mesh trial? 24 A. Yes. Boston Scientific, a trial in, I 25 think, Delaware or Rhode Island for Motley Rice.</p>	<p style="text-align: right;">Page 37</p> <p>1 A. No. I'm doing -- no, no, but Paxil, it's 2 still going on. They don't go away. 3 Q. Are you still doing work for anyone for 4 Paxil? 5 A. Yes. 6 Q. But not Clark, Love? 7 A. No. They're out, but it continues on. 8 Q. All right. Do you have any documents or 9 invoices reflecting compensation in this case, 10 either amounts billed and not paid or amounts billed 11 and paid? 12 A. You know, I didn't bring that. I did bring 13 my worksheet for just the last couple days which we 14 haven't billed for yet. 15 Q. All right. Dr. Parisian's handing me a 16 document that we'll mark as Exhibit 11. 17 (Whereupon, Exhibit No. 11 was marked 18 for identification.) 19 BY MR. GAGE: 20 Q. And this is a single sheet of paper that at 21 the top says, "Wagstaff & Cartmell. Attention Jeff 22 Kuntz, Attorney, re: Ethicon," and it reflects two 23 hours of work -- I'm sorry -- it reflects several 24 hours of work on March 6, 2016, and then several 25 hours of work on March 7, 2016?</p>

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<p style="text-align: right;">Page 38</p> <p>1 A. Yes, sir.</p> <p>2 Q. Okay. And I take it this is just an</p> <p>3 itemization of the amount of time you've spent over</p> <p>4 the last two days?</p> <p>5 A. Right. Yes, sir.</p> <p>6 Q. Okay. Do you have an itemization of how</p> <p>7 much time you spent before March 6 on Prolift+M?</p> <p>8 A. I believe there was a bill, and I don't -- I</p> <p>9 didn't bring the bill. I didn't look at the depo</p> <p>10 notice. I didn't bring the bill.</p> <p>11 Q. Okay.</p> <p>12 MR. GAGE: So I'll ask Nate and you to</p> <p>13 provide that to us.</p> <p>14 MR. JONES: Yep, we'll provide it.</p> <p>15 THE WITNESS: And that was sent to</p> <p>16 Clark, Love & Hutson, so I just didn't think of it.</p> <p>17 BY MR. GAGE:</p> <p>18 Q. Would that bill contain all of your time for</p> <p>19 fees and expenses apart from Exhibit -- what's been</p> <p>20 listed in Exhibit 11?</p> <p>21 A. Yes, sir.</p> <p>22 Q. All right. You don't happen to know or</p> <p>23 recollect how much that amount was in the invoice</p> <p>24 that you will be producing to me?</p> <p>25 A. No, sir. Because I don't make out the</p>	<p style="text-align: right;">Page 40</p> <p>1 I'm going through the book and drafting at the same</p> <p>2 time, so it's not like I broke them out separate.</p> <p>3 Q. Have you traveled anywhere for purposes of</p> <p>4 gathering information or for working on your</p> <p>5 Prolift+M --</p> <p>6 A. No.</p> <p>7 Q. -- report?</p> <p>8 Have you watched any videos?</p> <p>9 A. No.</p> <p>10 Q. Have you conducted any interviews?</p> <p>11 A. No.</p> <p>12 Q. Dr. Parisian, I read your TVT-Secur report</p> <p>13 in Garcia -- I'm sorry -- your TVT deposition in</p> <p>14 Garcia.</p> <p>15 A. Right, because there was no report. It was</p> <p>16 only disclosure.</p> <p>17 Q. Right.</p> <p>18 So I read your deposition there, and that</p> <p>19 deposition was in February of 2015, so from time to</p> <p>20 time, I may ask you some questions that appear to be</p> <p>21 duplicative, but the reason I ask them is because</p> <p>22 there's been a passage of a year and I just need to</p> <p>23 make sure that something hasn't changed since you</p> <p>24 last testified about some issues that are general in</p> <p>25 nature.</p>
<p style="text-align: right;">Page 39</p> <p>1 billing, so I don't know how much it was.</p> <p>2 Q. Can you estimate how long it took you to</p> <p>3 draft your -- or to review materials and draft your</p> <p>4 Prolift+M report?</p> <p>5 A. No. With the bill, I could probably, but I</p> <p>6 don't have it in front of me, so I don't know. It</p> <p>7 took a while.</p> <p>8 Q. Do you have an estimate of how many hours</p> <p>9 you've --</p> <p>10 A. No.</p> <p>11 Q. -- spent on Prolift+M?</p> <p>12 A. No.</p> <p>13 Q. But that would be reflected in the invoice</p> <p>14 to Clark, Love?</p> <p>15 A. Yes, sir.</p> <p>16 Q. Okay. So if I add whatever's in that</p> <p>17 invoice to Clark, Love to Exhibit 11, I'll have the</p> <p>18 entirety of everything that you have billed and/or</p> <p>19 worked with regard to Prolift+M in this case?</p> <p>20 A. Yes, sir.</p> <p>21 Q. Can you recollect, even if it's just by</p> <p>22 estimate, how much time you spent reviewing</p> <p>23 documents as opposed to how much time you've spent</p> <p>24 actually drafting your report?</p> <p>25 A. No, because I'm doing both at the same time.</p>	<p style="text-align: right;">Page 41</p> <p>1 In that deposition, you indicated that you</p> <p>2 had made over a million dollars over the last five</p> <p>3 years doing litigation work.</p> <p>4 Do you recall that testimony?</p> <p>5 A. I think the defense actually indicated it</p> <p>6 was a million.</p> <p>7 Q. Did -- had you made any sort of calculation</p> <p>8 on that?</p> <p>9 A. No, I haven't. Every year I've worked I've</p> <p>10 given the numbers, so it's no problem for defense to</p> <p>11 sit there and add up the numbers.</p> <p>12 Q. Right.</p> <p>13 A. And so I think the defense brought up that</p> <p>14 number. I don't know what it is. I mean, I haven't</p> <p>15 hidden anything. And last -- so --</p> <p>16 Q. Well, do you know what the -- since I'm</p> <p>17 trying to stitch together what happened in 2015 so</p> <p>18 we can bring that testimony forward, can you give us</p> <p>19 an estimate of the total amount you've earned doing</p> <p>20 litigation work in 2015?</p> <p>21 A. In 2015, it would have been about 700,000.</p> <p>22 That's how much the company brought in. I didn't</p> <p>23 keep all that. But I'm trying to cut back. That's</p> <p>24 what I testified in the depo, too, is I'm trying</p> <p>25 to -- actually, I was trying to retire, and so it's</p>

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<p style="text-align: right;">Page 42</p> <p>1 coming down, but not yet. But that was what it was 2 last year. 3 Q. Can you break out that \$700,000 for me and 4 just generally attach your earnings to various 5 pieces of litigation that you've worked on in 2015? 6 A. You mean -- 7 Q. So, for example -- I'm just giving you an 8 example -- "In 2015, I made 150,000 from mesh. I 9 made 150,000 from Plavix." 10 A. No, I can't do that. I didn't do Plavix 11 either, so, no, I can't really figure out which -- 12 you have my list, so -- you know, of all the cases 13 I've had. 14 Q. Do you know how much you've earned working 15 on the mesh litigation? 16 A. No. At one time I figured it out, but I 17 haven't done it recently. 18 Q. Can you give me an estimate of what 19 percentage of time in 2015 you spent working for any 20 mesh claim? 21 A. No, because as you know, I've done mesh for 22 a long time. I mean, with the -- I don't even know 23 what year AMS settled and all that stuff, so I've 24 been working on mesh for years. I did not figure up 25 the time, but I've been doing it longer than one</p>	<p style="text-align: right;">Page 44</p> <p>1 the cases I've been involved in are not active 2 anymore. 3 Wright Medical, that's a hip implant. Yes, 4 I'm still active in that. AMS pelvic mesh, that is 5 not active right now as far as I know. 6 Q. Is that because of a settlement? 7 A. Yeah. 8 Mirena, I'm still active in Mirena, which is 9 Bayer. The second case there would be a Bayer case, 10 same thing, Mirena. So all the American Medical 11 stuff is gone. Yasmin and YAZ, that's gone. 12 They're not doing that one anymore as far as I know. 13 PLEVA, I think the PLEVA cases are gone. 14 The generic Reglan cases as far as I know. C.R. 15 Bard, I am active in C.R. Bard. Those are the IVC 16 filter cases, so those would be things I'm still 17 active in. 18 Ethicon, Wright, so those are -- those are 19 basically what I'm active in now. Let's see. 20 Anything else? Abbott Laboratories, that's 21 Depakote. That's a birth defect case. I'm still 22 active in that. So -- Boston Scientific, yes, I'm 23 still active in that mesh, but only for Motley Rice. 24 And the Zometa and Aredia litigation, I 25 don't know what's going on with that stuff. I think</p>
<p style="text-align: right;">Page 43</p> <p>1 year. 2 Q. In 2015, I know I've got the places where 3 you've testified, but can you itemize for me the 4 various pieces of litigation where you're serving as 5 an expert witness in 2015 irrespective of whether 6 you've actually testified? 7 A. Usually the deposition list will talk about 8 what -- what I've been involved with because I 9 really am trying to cut my cases back. And so the 10 things I gave depositions are probably the active 11 cases that I had. 12 Q. You don't -- do you recall any work that you 13 did in 2015 for any piece of litigation where you 14 weren't deposed? 15 A. No. It seems like you write a report, and 16 then they want to depose you, so, no. 17 Q. So if I looked at your list of depositions, 18 that would give me an accurate picture of -- 19 A. Let me look at it before I answer. 20 All right. So I said my depositions; right? 21 So are you wanting to know what I'm active in right 22 now? 23 Q. Yes. 24 A. Is that what you're wanting? Okay. 25 Why don't we do it that way, because some of</p>	<p style="text-align: right;">Page 45</p> <p>1 all the ONJ cases are kind of gone. There's some 2 hip fractures cases that may be occurring. 3 And so those are the main active -- I have 4 fewer cases now than I used to, yeah, so those -- 5 those would be the ones that I'm active in. 6 I don't know what's going to happen with 7 Fosamax and the hip fractures. 8 Q. All right. Thank you. That was helpful. 9 A. Okay. So those are the witnesses I'm 10 still -- and Paxil came back, so I have Paxil again. 11 Apparently, it's re- -- come back. And then Kugel 12 Mesh came back. And so there's some Kugel Mesh 13 cases, and there's actually still one or two HRT 14 cases, hormonal placement therapy. 15 So I'm trying to cut -- so I have it down to 16 like less than ten. 17 Q. All right. Have you published any of the 18 opinions you're offering here today? 19 A. No. 20 Q. Have you spoken with any scientist, 21 engineer, or medical doctor regarding your opinions? 22 A. No. 23 Q. Is it correct to say that you developed 24 these opinions specifically for this litigation? 25 MR. JONES: Objection.</p>

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<p style="text-align: right;">Page 46</p> <p>1 THE WITNESS: Well, not -- it isn't 2 really, because, I mean, I've been involved with -- 3 the opinions about Prolift+M, yes, but as you know, 4 I've been involved in this type of issue for other 5 products. 6 BY MR. GAGE: 7 Q. Is it fair to say that your opinions were 8 not developed for some research project or study 9 that you are involved in? 10 A. Yes. 11 Q. Is it correct that you are not offering any 12 opinions on general causation or specific causation? 13 A. And I'll qualify that. That to me means 14 like medical causation for a particular plaintiff 15 because, obviously, I think that Prolift+M could 16 contribute. There could be complications like what 17 is seen in a patient. 18 But I don't see my role as a clinician in 19 terms of a particular case giving medical causation. 20 Is that what you're asking? 21 Q. Yes. 22 I will say that in the TVT-Secur deposition, 23 you answered that question or one similar to it by 24 saying that your opinions would be further developed 25 once you had reviewed the plaintiffs' medical</p>	<p style="text-align: right;">Page 48</p> <p>1 case-specific medical causation opinion? 2 A. That's correct. 3 Q. Okay. I also did not see anything in your 4 report about any manufacturing defect opinions, 5 where you would be offering an opinion that any 6 particular lot of Prolift+M had a manufacturing 7 defect. Is that correct? 8 A. That's correct. I've offered that in other 9 cases but not for this one. 10 Q. All right. 11 A. And, again, if -- that would be if there is 12 actually a specific plaintiff and I happen to look 13 at their lot, and then I would go look at -- and so 14 that's the one time that I did that in an AMS case. 15 Q. What was the opinion in summary that you 16 provided for a specific lot in a case? 17 A. It was a specific lot in that the -- it was 18 in Texas, and it had been kept out in the sales 19 rep's car, and so it had gotten hot. 20 And then we went back and looked at the 21 device history record. There had been a lot of 22 problems with the manufacturing of that particular 23 lot. So I went through the case reports and the 24 design history and manufacturing, and there -- most 25 of the lot had been rejected.</p>
<p style="text-align: right;">Page 47</p> <p>1 records. 2 MR. GAGE: Can -- and I suppose I 3 should -- I suppose I should have asked counsel if 4 they're willing to stipulate that Dr. Parisian will 5 not be reviewing plaintiff medical records and 6 offering case-specific opinions? 7 MR. AYLSTOCK: So stipulated. 8 MR. JONES: Yeah. 9 MR. GAGE: Okay. 10 MR. JONES: That's not in our plans. 11 THE WITNESS: Yeah. 12 And I look at it as the timing because 13 usually why I review the records is the timing 14 because a judge would want a case to be relevant to 15 that particular patient. 16 And so I'm not the causation, but I'm 17 looking at it, in terms of testimony, the period of 18 time. 19 BY MR. GAGE: 20 Q. Okay. So, for example, if there were 21 multiple IFUs, for example, in Prolift+M, you may 22 look at the medical records in order to determine 23 which was the applicable IFU. You may look at the 24 medical records. You may look at the depositions. 25 But it's not your intent to then provide a</p>	<p style="text-align: right;">Page 49</p> <p>1 And so this was a particular case where this 2 one was like, what? Why did you let that go? 3 Q. And for Prolift+M, at least to date, you 4 have not been asked to do such a case-specific 5 analysis? 6 A. That is correct. 7 Q. You're not here as a representative of FDA; 8 correct? 9 A. That is correct. 10 Q. Not speaking on behalf of FDA; correct? 11 A. That is correct. 12 Q. FDA has not reviewed or endorsed any of your 13 opinions in this case; correct? 14 A. That is correct. 15 Q. Have you ever spoken with anyone from FDA 16 regarding your opinions in this case? 17 A. No, and I would think that I would be 18 precluded from that, too, but I have not. 19 Q. Have you ever called or written to FDA about 20 any of your opinions in this case? 21 A. No. 22 Q. Were you invited by FDA to be part of a 2011 23 advisory committee concerning pelvic mesh? 24 A. No. 25 Q. Do you know why not?</p>

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<p style="text-align: right;">Page 50</p> <p>1 MR. JONES: Objection.</p> <p>2 THE WITNESS: No, I don't know why not.</p> <p>3 I wouldn't have put my name out there to be on it.</p> <p>4 For one thing, I'm not a urologist. I'm not a</p> <p>5 biomaterials person. And I just have not put myself</p> <p>6 out there where I would be that expert for that</p> <p>7 panel.</p> <p>8 BY MR. GAGE:</p> <p>9 Q. Have you ever been invited by FDA to be on</p> <p>10 an advisory committee of any type?</p> <p>11 A. I was at a meeting, an advisory meeting, to</p> <p>12 talk about device labeling, and so I was asked to</p> <p>13 come and talk about that. The FDA was trying to</p> <p>14 standardize device labeling to drug labeling, so</p> <p>15 that was -- and it's on my CV.</p> <p>16 Q. Do you remember what year that was?</p> <p>17 A. Oh, gosh. '97, '98. It wasn't recently.</p> <p>18 I'd feel very conflicted if I go to the FDA just</p> <p>19 because of all the stuff that I'm in, and it's</p> <p>20 better not to talk about anything.</p> <p>21 Q. Did you testify at that committee meeting?</p> <p>22 A. I was actually on the panel, so there is a</p> <p>23 transcript with my testimony in it.</p> <p>24 Q. Do you know where that transcript is?</p> <p>25 A. No. You probably could get it through -- at</p>	<p style="text-align: right;">Page 52</p> <p>1 Whereas, devices, there's all kinds of devices, so</p> <p>2 you're going to have problems if you try to make it</p> <p>3 the exact same format.</p> <p>4 Q. Dr. Parisian, I know that some of this was</p> <p>5 touched on during your TVT-Secur opinion, but I'm</p> <p>6 concerned that it may have been -- some of it in the</p> <p>7 context of Secur and not Prolift+M, so I'm going to</p> <p>8 re-ask some of these questions.</p> <p>9 At FDA were you ever involved with Prolift</p> <p>10 or Prolift+M?</p> <p>11 A. No.</p> <p>12 Q. Were you ever involved with any mesh</p> <p>13 products for pelvic organ prolapse?</p> <p>14 A. Not that I recall. I don't -- I don't</p> <p>15 recall.</p> <p>16 Q. When you were at the FDA, were you ever</p> <p>17 involved with mesh stress urinary incontinence</p> <p>18 devices?</p> <p>19 A. I don't think so, because I was there -- I</p> <p>20 left FDA in '95, and so the birth of mesh actually</p> <p>21 came after that. I've been involved with mesh but</p> <p>22 not necessarily for SUI. I've gone to meetings, I</p> <p>23 think at the NIH, about SUI issues but not</p> <p>24 specifically for this type of issue.</p> <p>25 Q. While you were at FDA, were you ever</p>
<p style="text-align: right;">Page 51</p> <p>1 the FDA.</p> <p>2 Q. All right. Have you ever seen that</p> <p>3 transcript?</p> <p>4 A. No.</p> <p>5 Q. Has anybody ever cross-examined you with</p> <p>6 that transcript?</p> <p>7 A. No.</p> <p>8 Q. All right.</p> <p>9 A. I know what I said, and, so, no, I didn't --</p> <p>10 Q. Recognizing that we have -- we're under a</p> <p>11 tight time limit, can you give me a summary of what</p> <p>12 you testified to at that meeting that is less than</p> <p>13 30 seconds in length?</p> <p>14 A. They were -- yeah, sure.</p> <p>15 They were trying to make device labeling</p> <p>16 like drug labeling, and there were difficulties in</p> <p>17 terms of that. In terms of writing an adequate</p> <p>18 device label, it's tricky compared to a drug label,</p> <p>19 and so that was my -- my discussion was the</p> <p>20 difference between a drug label and a device label.</p> <p>21 Q. And, again, in a summary fashion, what are</p> <p>22 the differences in your opinion?</p> <p>23 A. It's -- it's just -- there's -- it's just a</p> <p>24 drug label is fairly standard. It's a pill, and you</p> <p>25 give the same kind of information over and over.</p>	<p style="text-align: right;">Page 53</p> <p>1 involved with pelvic floor repair devices?</p> <p>2 A. Not devices, no. I had gone to meetings</p> <p>3 talking about pelvic floor repair but not devices.</p> <p>4 Q. After you left FDA, is it correct to say</p> <p>5 that you had no involvement with FDA's review of</p> <p>6 Prolift or Prolift+M or any of the mesh devices?</p> <p>7 A. That's correct.</p> <p>8 Q. Have you ever drafted a label or an IFU for</p> <p>9 a surgically implantable device?</p> <p>10 A. In clinical trials.</p> <p>11 Q. What was that device?</p> <p>12 A. It was a device that was being used as a</p> <p>13 shunt in the brain, CNS shunt, and it was being used</p> <p>14 in elderly people to try to do clinical trials for</p> <p>15 Alzheimer's disease, and that's the only one I can</p> <p>16 recall, and I was a consultant.</p> <p>17 Q. What was the company?</p> <p>18 A. It was Stanford University. They were</p> <p>19 trying a clinical trial, so it wasn't a company per</p> <p>20 se.</p> <p>21 Q. So it was a medical device that they had</p> <p>22 created and wanted to run some clinical trials on?</p> <p>23 A. Well, they had me help them create the</p> <p>24 medical device, and then they wanted to run some</p> <p>25 trials to see if they could reduce Alzheimer's</p>

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<p style="text-align: right;">Page 54</p> <p>1 spread, and so I was involved with them.</p> <p>2 Q. Did you help create an IFU?</p> <p>3 A. For the investigators, yes, sir.</p> <p>4 Q. Where could I get a copy of that?</p> <p>5 A. I don't know if you can. It was an IDE, and</p> <p>6 I don't think it really took off. I don't know what</p> <p>7 happened to it.</p> <p>8 Q. Do you have a copy of it?</p> <p>9 A. I don't have a copy of it. It was back in,</p> <p>10 like, '96.</p> <p>11 Q. There was some discussion -- well, there was</p> <p>12 some discussion during your TVT-Secur deposition of</p> <p>13 your working for a company called "Insurex."</p> <p>14 A. SURx, yeah, S-U-R-x.</p> <p>15 Q. S-U-R-x?</p> <p>16 A. Right.</p> <p>17 Q. Right. I think that transcript incorrectly</p> <p>18 called it "Insurex," I-n-s-u-r-e-x.</p> <p>19 A. No. You will never find it. S-U-R-x.</p> <p>20 Q. S-U-R-x?</p> <p>21 A. It's a radiofrequency device for using a</p> <p>22 radiofrequency current to try to control a woman's</p> <p>23 SUI, in terms of that, so -- and I was brought in as</p> <p>24 a consultant because they had gotten rejected by the</p> <p>25 FDA, and I was to come in and help clean up the data</p>	<p style="text-align: right;">Page 56</p> <p>1 A. No.</p> <p>2 Q. Do you know where I could get a copy of it?</p> <p>3 A. No. I don't even know if the company is</p> <p>4 still making it or if they sold it.</p> <p>5 Q. Have you ever drafted a patient brochure for</p> <p>6 a surgically implantable device?</p> <p>7 A. At the FDA I commented on them in terms of</p> <p>8 surgically implantable devices. I have not drafted</p> <p>9 it from square one. But in terms of medical</p> <p>10 devices, you're often more interactive with</p> <p>11 companies in terms of -- like, I know I was involved</p> <p>12 with implantable cardiac defibrillators when they</p> <p>13 first came out and also some of the -- so those</p> <p>14 would have been issues that I was looking at the</p> <p>15 labels, but I didn't draft them.</p> <p>16 Q. Do you -- could you identify for me any --</p> <p>17 and I assume while you were at FDA you also looked</p> <p>18 at and commented upon instructions for use with</p> <p>19 regard to medical devices?</p> <p>20 A. Yes, sir.</p> <p>21 Q. Is there -- can you identify for me any</p> <p>22 instructions for use or patient brochures that you</p> <p>23 reviewed, edited, and/or approved while you were at</p> <p>24 FDA?</p> <p>25 A. That's really hard. I don't know, I mean,</p>
<p style="text-align: right;">Page 55</p> <p>1 so they could get cleared.</p> <p>2 Q. Do you recall what year or years that</p> <p>3 occurred?</p> <p>4 A. No. It would have been, like, in the '90s.</p> <p>5 It was when I first left the FDA.</p> <p>6 Q. Did you assist that company in drafting</p> <p>7 instructions for use for that device?</p> <p>8 A. Yes. But more importantly, I had to look at</p> <p>9 their data because that was the issue that they had</p> <p>10 gotten in trouble with with the FDA. So we cleaned</p> <p>11 up their data.</p> <p>12 I don't remember if it was PMA or a 510(k),</p> <p>13 but it got cleared.</p> <p>14 Q. Do you -- did you in that case review or</p> <p>15 comment on the IFU?</p> <p>16 A. It was a training manual, yeah, so I looked</p> <p>17 at the training manual because you have to be able</p> <p>18 to comment on how doctors can do it. My main focus,</p> <p>19 though, was the clinical data.</p> <p>20 Q. Did you provide edits or input to the</p> <p>21 training manual?</p> <p>22 A. Yes. I looked at it and gave what my</p> <p>23 thoughts were, but in terms of -- again, it was the</p> <p>24 data that I had to look at.</p> <p>25 Q. Do you have a copy of that training manual?</p>	<p style="text-align: right;">Page 57</p> <p>1 because I -- that would have been my routine to look</p> <p>2 at the IFU and make comments because I looked at</p> <p>3 IFUs post market for people who needed warnings and</p> <p>4 had gotten into safety issues and looked at them</p> <p>5 premarket.</p> <p>6 I remember being involved with Cook</p> <p>7 Catheter. They had an amniotic -- chorionic villus</p> <p>8 sampling device. I remember working on that in</p> <p>9 terms of the approval. That was a PMA product.</p> <p>10 That would have been there. But, no. That was --</p> <p>11 routine exam was that you would look at the labeling</p> <p>12 and make comments.</p> <p>13 But more in postmarket, when people got into</p> <p>14 recall issues, I would always say, "Put a warning,"</p> <p>15 or do stuff, so it would have been more in my</p> <p>16 postmarket days.</p> <p>17 Q. Dr. Parisian, I know much of this was</p> <p>18 covered at your prior deposition, but, again, it's</p> <p>19 been a gap of a year's time, and I want to make sure</p> <p>20 nothing has changed.</p> <p>21 Are you still a licensed medical doctor?</p> <p>22 A. Yes.</p> <p>23 Q. And you are a pathologist; correct?</p> <p>24 A. Yes.</p> <p>25 Q. You have not gotten any new certifications</p>

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<p style="text-align: right;">Page 58</p> <p>1 or training in the last year since you were deposed 2 in the Garcia case? 3 A. That's correct. 4 Q. Have you treated any patients since 1988? 5 A. Not as -- I've treated my family, but not as 6 a -- no, I don't have a clinical practice. 7 Q. All right. And do you have any current 8 board certifications? 9 A. Yeah. I'm board certified, anatomic and 10 clinical pathology. 11 Q. Any staff privileges at any hospital? 12 A. No. 13 Q. Are you credentialed at any hospital? 14 A. No. 15 Q. Did you ever participate in a cadaver study 16 regarding any mesh device? 17 A. No. A lot of cadavers but not with mesh. 18 Q. Ever participate in any animal studies 19 regarding any mesh device? 20 A. No. 21 Q. Ever design any clinical trials or protocols 22 or studies regarding any device involving mesh? 23 A. No. 24 Q. Ever involved in any clinical research 25 regarding mesh?</p>	<p style="text-align: right;">Page 60</p> <p>1 device that was either polypropylene or synthetic 2 surgical mesh? 3 A. Correct. 4 Q. And you did no mechanical testing of the 5 mesh in Prolift+M? 6 A. Correct. 7 Q. You did not do any type of testing or 8 measurements on the mesh in Prolift+M? 9 A. Correct. 10 Q. And that's not something you would do in 11 your normal practice? 12 A. Correct. 13 Q. Have you ever diagnosed pelvic organ 14 prolapse? 15 A. Well, yes. 16 Q. When was that? 17 A. When I used to do OB/G -- and when I did GYN 18 exams. 19 Q. When was that? 20 A. That would be in the '80s. I mean, I had a 21 clinic, and so we would see women all the time for 22 GYN clinic day. So, yeah, I've seen prolapse. 23 Q. Did you ever treat it? 24 A. Not with mesh or surgically treat it, no. 25 If a woman had problems, then you would send her to</p>
<p style="text-align: right;">Page 59</p> <p>1 A. No. 2 Q. Ever designed mesh? 3 A. No. 4 Q. And I think you testified earlier you've 5 never done any biomechanical testing of mesh. Is 6 that correct? 7 A. That's correct. 8 Q. No lab work regarding mesh? 9 A. That's correct. 10 Q. Have you done any testing of a polypropylene 11 or mesh explant? 12 A. No. 13 Q. And do you know what I mean when I say 14 "explant"? 15 A. Yeah, sure. Somebody who's removed it, like 16 a surgical specimen. No. 17 Q. Have you ever inspected polypropylene or a 18 mesh explant of any kind? 19 A. No. 20 Q. Have you ever looked at explanted mesh under 21 a microscope? 22 A. No. 23 Q. Is it correct to say that you've never been 24 involved in a clinical trial to evaluate the safety 25 or efficacy of a medical device or part or all of a</p>	<p style="text-align: right;">Page 61</p> <p>1 a urologist at that time. That was in the '80s. 2 Q. Did you ever perform any surgery to treat 3 pelvic organ prolapse? 4 A. No. 5 Q. Do you believe that today you have the 6 requisite education, training, and experience to 7 counsel a patient about the treatment options for 8 pelvic organ prolapse? 9 A. I wouldn't engage in that. I'm a regulatory 10 expert. I'm not going to consult with patients 11 about it. 12 Q. Have you ever implanted a medical device 13 used to treat pelvic organ prolapse? 14 A. No. We used to use pessaries and things for 15 that, and -- but that was not implanted. 16 Q. Do you consider yourself an expert in pelvic 17 organ prolapse? 18 A. No. 19 Q. Have you ever implanted or explanted any 20 medical device? 21 A. I don't know. I mean, it wouldn't have been 22 a major -- I mean, there's some devices that are 23 small that you would have implanted or -- I don't 24 know. I mean, it's a long time ago. 25 Q. When was the first time you heard of Prolift</p>

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<p style="text-align: right;">Page 62</p> <p>1 or Prolift+M?</p> <p>2 A. When I was asked to look at it.</p> <p>3 Q. In litigation?</p> <p>4 A. Yes, sir.</p> <p>5 Q. Any idea as to how many Prolift+M devices</p> <p>6 have been implanted in the United States or in the</p> <p>7 world?</p> <p>8 A. No, sir.</p> <p>9 Q. Have you ever seen a Prolift or Prolift+M</p> <p>10 implanted in the body in a live setting?</p> <p>11 A. No.</p> <p>12 Q. Have you ever watched a video of a Prolift</p> <p>13 or Prolift+M procedure?</p> <p>14 A. No.</p> <p>15 Q. Have you ever held a Prolift or Prolift+M</p> <p>16 device in your hand?</p> <p>17 A. No.</p> <p>18 Q. Have you ever been in the same room with a</p> <p>19 Prolift or Prolift+M device?</p> <p>20 A. No. Nobody at the FDA would be either.</p> <p>21 MR. AYLSTOCK: Whenever you get to a</p> <p>22 breaking point, my coffee is out.</p> <p>23 MR. GAGE: That's fine. Why don't we</p> <p>24 stop. Yeah, let's take a quick one here.</p> <p>25 (Short recess was taken.)</p>	<p style="text-align: right;">Page 64</p> <p>1 BY MR. GAGE:</p> <p>2 Q. Dr. Parisian, I'm handing you just a chart</p> <p>3 of the pelvic anatomy that I've marked as</p> <p>4 Exhibit 12.</p> <p>5 Are you familiar with the pelvic floor</p> <p>6 anatomy?</p> <p>7 A. As a pathologist, yes, sir.</p> <p>8 Q. Are you familiar with the POP-Q system?</p> <p>9 A. The POP-Q system?</p> <p>10 Q. Yes.</p> <p>11 A. No.</p> <p>12 Q. Do you know what that is?</p> <p>13 A. I know what POP is, but I don't know what</p> <p>14 the Q part is.</p> <p>15 Q. All right. So if I were to ask you to draw</p> <p>16 for me on this chart the various points, such as</p> <p>17 point AA, point BA, point C, point D, under the</p> <p>18 POP-Q system, would you be able to do that?</p> <p>19 A. No.</p> <p>20 Q. All right.</p> <p>21 (Whereupon, Exhibit No. 13 was marked</p> <p>22 for identification.)</p> <p>23 BY MR. GAGE:</p> <p>24 Q. Dr. Parisian, I'm handing you Exhibit 13.</p> <p>25 Do you know what that is?</p>
<p style="text-align: right;">Page 63</p> <p>1 BY MR. GAGE:</p> <p>2 Q. Dr. Parisian, would you agree that there are</p> <p>3 patients who have had Prolift+M implanted who have</p> <p>4 had no complications?</p> <p>5 A. I don't know.</p> <p>6 Q. Would you agree that there are patients who</p> <p>7 have had good experiences with Prolift+M?</p> <p>8 A. I don't know. That would be the urologist</p> <p>9 and gynecologists talking about that.</p> <p>10 Q. Would you agree that there are women who</p> <p>11 have a Prolift+M placed where it has been a safe and</p> <p>12 effective device for them?</p> <p>13 A. I don't know.</p> <p>14 Q. Would you agree that there are a significant</p> <p>15 number of doctors in the United States who believe</p> <p>16 the Prolift+M was safe and effective?</p> <p>17 A. You know, I don't know, but I mean, the FDA</p> <p>18 is going to reclassify all these POP devices in</p> <p>19 order to have a PMA. So FDA doesn't agree with</p> <p>20 that, so I don't know.</p> <p>21 And so you're asking me questions. Who</p> <p>22 knows? You have to have follow-up. So I don't</p> <p>23 know.</p> <p>24 (Whereupon, Exhibit No. 12 was marked</p> <p>25 for identification.)</p>	<p style="text-align: right;">Page 65</p> <p>1 A. This is -- this is -- I don't know if it's</p> <p>2 Prolift+M or Prolift. This is the pelvic floor,</p> <p>3 what it looks like in the 510(k) in terms of the</p> <p>4 diagrams. I'm not sure which one it is</p> <p>5 particularly, but it would be the different pelvic</p> <p>6 floor mesh configurations with the arms like -- so</p> <p>7 that's what it is.</p> <p>8 Q. Are you able to discern as between these</p> <p>9 three which is the Prolift total -- Prolift+M total,</p> <p>10 the Prolift+M anterior, and the Prolift+M posterior?</p> <p>11 MR. JONES: Objection.</p> <p>12 THE WITNESS: Well, my guess would be</p> <p>13 that the first one with all the stuff is the total.</p> <p>14 And I'm not -- I'm not sure which one would be the</p> <p>15 anterior and which would be the posterior.</p> <p>16 I'm guessing. I mean, I'm not the</p> <p>17 person that would be doing this, but -- so I think</p> <p>18 the one that's got the biggest one here, that would</p> <p>19 be total.</p> <p>20 BY MR. GAGE:</p> <p>21 Q. All right.</p> <p>22 A. Because it's got everything on it.</p> <p>23 Q. And the one that you're pointing to is the</p> <p>24 one on the far left?</p> <p>25 A. Yes, sir.</p>

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<p style="text-align: right;">Page 66</p> <p>1 Q. All right. Dr. Parisian, I read your 2 Prolift+M report, and is it -- it's correct to say 3 that you are critical of both the Prolift+M 4 instructions for use and the Prolift+M patient 5 brochure. 6 Is that a fair statement? 7 A. Oh, I think we start further back than that. 8 I think the design and the development of 9 the product, the -- and the information being 10 provided to the physicians from what the company 11 knew in Europe. 12 So, yes, I am critical of that, but it 13 starts back further than just the brochure and the 14 IFU. 15 Q. Okay. 16 MR. GAGE: So move to strike as 17 nonresponsive. 18 BY MR. GAGE: 19 Q. Just focusing in on the IFU and the patient 20 brochure, is it correct to say that you are critical 21 of the IFU and the patient brochure for Prolift+M? 22 A. Yes. 23 Q. Okay. Have you drafted an IFU or a patient 24 brochure for Prolift+M that you believe is adequate? 25 A. No.</p>	<p style="text-align: right;">Page 68</p> <p>1 particular case. I mean, that's usually what has 2 happened. 3 If a physician said, "I needed to know 4 this, I needed to know that," then I'll look at 5 the IFU and I'll say, "It's not there," the 6 information that they were asking about. 7 And then the other thing that I usually 8 testify to are the types of information that are 9 specific to Prolift+M that are not in the label. 10 And so I would give that. 11 But have I written a label, no, and it 12 would usually be, "This is the types of information 13 that a physician would need to know." Usually it's 14 reinforced by what the physician says, and then it 15 needs to be made specific for Prolift+M. 16 What are the things that you're having 17 in the literature, the reports? What was it that 18 they knew in France? I think I said about the 2D 19 imaging, that you could look at the 2D imaging and 20 see if the person was having the -- the product 21 eroding. 22 So there are some things in my report 23 as to things that would need to be in an adequate 24 IFU, but I haven't written an adequate IFU for it. 25 ///</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. Have you provided -- or strike that. 2 Do you have a document that you have edited 3 that would show edits or changes to the existing 4 Prolift+M IFU or patient brochure that would, if 5 adopted, make it adequate? 6 A. No. 7 Q. Do you intend to testify before a jury that 8 the inclusion of specific words or the removal of 9 specific words in either the IFU or the patient 10 brochure would be necessary in order to make those 11 documents adequate? 12 MR. JONES: Objection. 13 BY MR. GAGE: 14 Q. Do you understand what I'm saying? 15 I'm trying to understand whether you intend 16 to testify to a jury, "Here's -- here's the list of 17 the -- of the specific words that they should have 18 included in an IFU in order for it to be adequate," 19 or "Here's a list of the words that should have been 20 taken out of the Prolift+M IFU in order to make it 21 adequate." 22 MR. JONES: Objection. 23 THE WITNESS: I mean, a lot of it is 24 going to depend on what the physicians say, what 25 they think they should have known for their</p>	<p style="text-align: right;">Page 69</p> <p>1 BY MR. GAGE: 2 Q. Have you ever spoken with a doctor who has 3 implanted a Prolift or a Prolift+M device? 4 A. No. 5 Q. Have you read the depositions of any doctors 6 who have implanted Prolift or Prolift+Ms? 7 A. No. 8 (Whereupon, Exhibit No. 14 was marked 9 for identification.) 10 BY MR. GAGE: 11 Q. All right. Dr. Parisian, I'm going to hand 12 you a chart I marked as Exhibit 14. I will confess 13 to that I -- it's in my own handwriting, and I only 14 have one copy which you and Nate can look at at the 15 same time. And I may have to come around on your 16 side of the table so I can kind of look at it. 17 But I want you to just take a look at it and 18 I'll give you a second to read it. 19 A. Okay. 20 Q. So, Dr. Parisian, what I've got there is a 21 circle divided into, I guess, eight piecharts -- or 22 pie slices, and I've gotten -- I've written in 23 that -- in those piecharts, IFU, Prof. Ed, which 24 means professional education, then med 25 school/training, then med lit, which means medical</p>

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<p style="text-align: right;">Page 70</p> <p>1 literature, then colleagues, then experience, then 2 patient brochure, and then I think I wrote Surgeon's 3 Resource Monograph. 4 Do you see that? 5 A. Yes, sir. 6 Q. Okay. Do you agree that -- and I think at 7 the title, it says, "Sources of Risk Information." 8 Is that correct? 9 A. That's what your title is. 10 Q. All right. Do you agree that -- well, first 11 of all, you understand what professional education 12 is? 13 A. Yes, sir. 14 Q. Okay. And, obviously, you know -- you are 15 generally familiar with all the other components of 16 that pie chart. Is that correct? 17 A. Yes, sir. 18 Q. Are you familiar -- 19 A. Now, are you talking about just 20 hypothetically in general? 21 Q. In general. 22 A. Because it doesn't really reflect what's 23 happening with Prolift+M. 24 Q. That's correct. 25 A. Okay.</p>	<p style="text-align: right;">Page 72</p> <p>1 they're going to, actually, training classes. 2 Q. Maybe you and I are missing each other a 3 little bit. 4 A. Probably. 5 Q. I had referred -- when I was referring to 6 Prof. Ed, I was referring to the Ethicon 7 professional education, which would include 8 everything that would fall underneath that umbrella, 9 such as, you know, didactics, seminars, sales force 10 interaction, and that sort of thing. 11 If I wrote "Ethicon" above "Prof. Ed," would 12 that help fill out that piece of pie chart for you? 13 A. It would be better, but I think it would be 14 much bigger, because in this particular case, the 15 surgeon is actually dependent on the company to give 16 them all the training and to develop the procedure. 17 Q. All right. So what I've done is I've 18 written in "Ethicon" above "Prof. Ed." I think that 19 would -- that cures at least some of your concern 20 about the chart; correct? 21 A. If you're talking that's the cadaver lab, 22 that's where they're training -- okay, all right. 23 MR. JONES: Sales reps -- 24 THE WITNESS: Sales reps. 25 MR. JONES: -- sales reps, I think, is</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. I'm just talking about in general. 2 A. Okay. 3 Q. Are you familiar with the Surgeon's Resource 4 Monograph? 5 A. Right. That would be your training manual 6 for the surgeon. 7 Q. Yes. 8 Did you -- is that one of the documents you 9 reviewed? 10 A. I reviewed it, but I'm not a surgeon, but in 11 terms of -- I mean, because one of the things 12 missing here is your sales force, and that company 13 is doing the training course. 14 And so this is -- this -- this diagram is 15 more typical of traditional -- like a urologist 16 practice or something. 17 But in terms of these cases where the -- the 18 company is the one responsible for the procedure and 19 the training and stuff, it doesn't really reflect 20 the company's involvement. 21 Q. All right. So let's -- I take it we need to 22 add the sales force to that chart? 23 A. I think it would be a big piece of pie on 24 this and also their courses that they have, because 25 your resource monograph is just the book, but</p>	<p style="text-align: right;">Page 73</p> <p>1 the -- 2 THE WITNESS: Is missing. 3 MR. JONES: -- is the issue. 4 BY MR. GAGE: 5 Q. So we'll call it "Ethicon Prof. Ed," and 6 what would be the words you would like to put in 7 there? Sales reps? Sales training? How would 8 you -- 9 A. It would be a bigger piece of the pie 10 because in this -- 11 Q. I'm going to let you -- I'm going to ask you 12 later to give me some -- I'm going to let you in a 13 sense adjust the sizes of the piece of the pie in 14 just a minute. 15 So I just want to get the pieces of the pie 16 properly dominated at this point. 17 A. Well, let me see. Where would you -- I 18 mean, you don't have sales reps there. 19 Q. I know. I had included sales -- in my mind, 20 I included sales reps under "Prof. Ed." 21 MR. JONES: Under professional 22 education? 23 I think in her mind maybe they're -- 24 maybe that's the disconnect. Because she can help 25 you fill out this chart, and that's what she's</p>

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<p style="text-align: right;">Page 74</p> <p>1 trying to do.</p> <p>2 BY MR. GAGE:</p> <p>3 Q. What words can I put into that Ethicon Prof.</p> <p>4 Ed that would encompass in your mind the totality of</p> <p>5 what's coming from the company in that section?</p> <p>6 I'm not trying to trick --</p> <p>7 MR. JONES: And don't feel constrained</p> <p>8 by his terms. You know, you're getting caught up on</p> <p>9 he's made them all equal spaces, so don't be</p> <p>10 confined with trying to fill in his charts the way</p> <p>11 he has done it.</p> <p>12 THE WITNESS: Well, let me do it,</p> <p>13 because this -- this big piece of the pie is the --</p> <p>14 is more the sales rep, because they're -- they go</p> <p>15 through the IFU. They go through the monograph with</p> <p>16 the doctor.</p> <p>17 So they're the ones who -- this would</p> <p>18 all be sales reps would be doing this, because they</p> <p>19 make the thing for the people to go to courses.</p> <p>20 They're -- so they're all setting it up, selling</p> <p>21 this thing here.</p> <p>22 BY MR. GAGE:</p> <p>23 Q. Okay.</p> <p>24 A. Okay. So that would be the sales rep. All</p> <p>25 of this stuff would be them.</p>	<p style="text-align: right;">Page 76</p> <p>1 a bigger piece. So you've now got the doctor</p> <p>2 involved with this thing that mainly comes from</p> <p>3 Ethicon. They don't know anything about it.</p> <p>4 And so, yes, they are trained. They're a</p> <p>5 licensed doctor. The medical literature, there</p> <p>6 isn't really any. Colleagues, most of their</p> <p>7 colleagues don't know about a new thing either. So</p> <p>8 this is -- this is the big -- it's almost half the</p> <p>9 pie.</p> <p>10 Q. All right. So -- and, again, you just --</p> <p>11 the -- everything in red is your handwriting with</p> <p>12 the exception of where I wrote the word "Ethicon";</p> <p>13 correct?</p> <p>14 A. Yes, sir.</p> <p>15 Q. And I think you've explained why you group</p> <p>16 those together, and sales reps run across those four</p> <p>17 pieces of the pie that you've marked in red?</p> <p>18 A. Right.</p> <p>19 Q. All right. Okay. Are there any other</p> <p>20 sources of risk information that you think is</p> <p>21 missing?</p> <p>22 MR. JONES: Objection.</p> <p>23 THE WITNESS: Sources of risk</p> <p>24 information?</p> <p>25 Well, as -- as in my report, when I</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. All right. And just for the record, what</p> <p>2 you've done is you've written "sales reps" over</p> <p>3 "Surgeon's Resource Monograph, IFU, and Ethicon</p> <p>4 Prof. Ed"?</p> <p>5 A. Right.</p> <p>6 Q. Do you want to -- I've wrote the word "and."</p> <p>7 Do we need to delete -- strike through the</p> <p>8 word "and"?</p> <p>9 A. There we go. We get rid of that.</p> <p>10 Q. Okay.</p> <p>11 A. But, see, I look at this as this is a big</p> <p>12 part of the pie. The medical -- they're trained --</p> <p>13 they're doctors, yes. Medical literature, when you</p> <p>14 learn these procedures, there's not a lot of medical</p> <p>15 literature. And in terms of the Prolift+M, most of</p> <p>16 that had been done in France.</p> <p>17 Q. Okay. We'll get -- I'll get back to the</p> <p>18 specifics of each of the piecharts. I just wanted</p> <p>19 to understand what your view was of the -- of the</p> <p>20 pie chart.</p> <p>21 Now, you're still --</p> <p>22 A. Because the patient brochure comes from</p> <p>23 Ethicon too.</p> <p>24 Q. Got it.</p> <p>25 A. So we have to -- so that made it a bigger --</p>	<p style="text-align: right;">Page 77</p> <p>1 talk about -- if we're talking specifically about</p> <p>2 Prolift+M, the thing that's missing is a lot of the</p> <p>3 European data. That -- that is not being given to</p> <p>4 the physicians in terms of experience. So they're</p> <p>5 not getting the foreign experience in terms of the</p> <p>6 physicians having problems with the Prolift+M.</p> <p>7 BY MR. GAGE:</p> <p>8 Q. But I think that -- I think it would be your</p> <p>9 opinion, would it not, that that's something that</p> <p>10 Ethicon should be providing in either the Prof. Ed,</p> <p>11 the IFU, the Surgeon's Resource Monograph or the</p> <p>12 patient brochure; right?</p> <p>13 A. It's my opinion they should, but they</p> <p>14 didn't.</p> <p>15 And the Prolift -- the Prolift is where this</p> <p>16 all comes from, and that had been off label. That</p> <p>17 had been no real training, no real development.</p> <p>18 So you have American physicians that are</p> <p>19 getting into the Prolift and, you know, they</p> <p>20 didn't -- they didn't have that -- that wealth of</p> <p>21 experience from France, and so experience is one</p> <p>22 thing, because I assume you're talking about the</p> <p>23 doctor's experience doing procedures?</p> <p>24 Q. That's correct.</p> <p>25 The sources of risk information that are</p>

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<p style="text-align: right;">Page 78</p> <p>1 available to doctors.</p> <p>2 A. Right, and that would be his medical</p> <p>3 experience, but I think the history of the use of</p> <p>4 the device outside the country, that was not being</p> <p>5 given to the doctors. It wasn't given to the FDA</p> <p>6 either.</p> <p>7 So, you know, this experience part here</p> <p>8 is -- you know, you're talking about their</p> <p>9 experience, so this would be --</p> <p>10 Q. I'm talking about the surgeon --</p> <p>11 A. Right.</p> <p>12 Q. -- the individual surgeon's experience.</p> <p>13 A. Right. Right here. He's --</p> <p>14 MR. JONES: Experience with -- sorry.</p> <p>15 Experience with what?</p> <p>16 THE WITNESS: Yeah.</p> <p>17 Surgeon experience because most of</p> <p>18 these surgeons don't have any experience with this</p> <p>19 stuff, and there's a huge learning curve.</p> <p>20 So this would be your French data,</p> <p>21 European data, the learning curve, learning curve.</p> <p>22 The other thing is that only 10 to 20 percent of the</p> <p>23 physicians were being asked, and they were all very</p> <p>24 experienced.</p> <p>25 So you have no surgeon experience,</p>	<p style="text-align: right;">Page 80</p> <p>1 MR. JONES: Objection.</p> <p>2 THE WITNESS: You know, I would leave</p> <p>3 that to a surgeon to explain that, but I know that</p> <p>4 in terms of Europe, the surgeons that they had used</p> <p>5 were very experienced, and they had difficulty with</p> <p>6 the product, and there was a huge learning curve.</p> <p>7 And I know when they went to marketing</p> <p>8 in the United States, they were looking for surgeons</p> <p>9 who did not have experience, who had not wanted to</p> <p>10 use mesh.</p> <p>11 So they were targeting doctors who</p> <p>12 weren't necessarily that experienced in it, so</p> <p>13 that's why the pie kind of changes because</p> <p>14 experience, they're not giving the surgical</p> <p>15 experience in the vast, and I think that that was</p> <p>16 what was big about the Prolift+M.</p> <p>17 BY MR. GAGE:</p> <p>18 Q. Are you aware that some doctors do not read</p> <p>19 the IFUs or patient brochures before implanting</p> <p>20 surgical mesh?</p> <p>21 MR. JONES: Objection.</p> <p>22 THE WITNESS: You know, in terms of the</p> <p>23 surgical field, oftentimes the IFU is implanted</p> <p>24 sterile, and so if you ask --</p> <p>25 ///</p>
<p style="text-align: right;">Page 79</p> <p>1 which is a whole other horse of a different color.</p> <p>2 The colleagues -- you know, Ethicon actually has</p> <p>3 some input, what their colleagues are telling them,</p> <p>4 so we don't know what -- Ethicon's input to that.</p> <p>5 So, I mean, that's why you have to</p> <p>6 divide the experience as to what actually happened</p> <p>7 with the device, that only 10 to 20 percent were</p> <p>8 being trained how to use it. They were having</p> <p>9 significant learning curves.</p> <p>10 So now if you talk about a new surgeon</p> <p>11 experience, he may not have had it. He didn't have</p> <p>12 any experience.</p> <p>13 BY MR. GAGE:</p> <p>14 Q. Could a surgeon gather any -- could a</p> <p>15 surgeon implant, for example, another manufacturer's</p> <p>16 device and have any of that experience carry over to</p> <p>17 the understanding of the risks of Prolift+M?</p> <p>18 A. In terms of the 10 to 20 percent that they</p> <p>19 selected, the company, to train in Europe, those</p> <p>20 people had experience with other devices.</p> <p>21 Q. Well, I'm just talking about in general.</p> <p>22 If a surgeon, for example, had implanted</p> <p>23 1,000 pelvic meshes before that were not Prolift+M</p> <p>24 but then implanted a Prolift+M, would there be any</p> <p>25 translatable experience?</p>	<p style="text-align: right;">Page 81</p> <p>1 BY MR. GAGE:</p> <p>2 Q. You said the IFU is implanted sterile?</p> <p>3 A. Well, it is sterile. It's in the sterile</p> <p>4 package. And so they're not going to sit in an OR</p> <p>5 and read it.</p> <p>6 They tend to read it outside of the OR, so</p> <p>7 some doctors will say, yeah, I didn't read the IFU</p> <p>8 in the OR because it costs money to sit there and</p> <p>9 read the IFU.</p> <p>10 You already decide you're going to use it,</p> <p>11 so they may have read marketing at some point in</p> <p>12 time, but the IFU still was required to be adequate</p> <p>13 instructions and warnings by the regulations</p> <p>14 whenever they read it.</p> <p>15 Q. Do all doctors read the IFUs?</p> <p>16 A. You know --</p> <p>17 MR. AYLSTOCK: Objection.</p> <p>18 THE WITNESS: -- I can't answer for all</p> <p>19 IFUs. I just can answer what is required of an IFU.</p> <p>20 BY MR. GAGE:</p> <p>21 Q. All right. Let me ask, is it acceptable</p> <p>22 medical practice for a pelvic floor surgeon to</p> <p>23 implant a Prolift+M without first reading the</p> <p>24 IFU?</p> <p>25 A. It depends. It depends in what they've been</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 told, if they've gone to training courses. It 2 depends, you know, to say that they've obviously had 3 some training, so each case is going to have a 4 surgeon that's going to answer that question. 5 Q. All right. So if a surgeon testified in a 6 particular case that he or she did not read the IFU, 7 that wouldn't necessarily trouble you? 8 MR. JONES: Objection. 9 MR. AYLSTOCK: Objection to form. 10 THE WITNESS: Oftentimes -- not 11 necessarily because oftentimes they will be talking 12 about an IFU that was in the surgery. You're not 13 going to read it there. And then oftentimes you 14 back them up, and you go, "Well, did you go to a 15 course? Did you rely on the sales reps?" 16 So it's -- the other things are 17 important besides the IFU. The sales rep is a huge 18 entity in terms of this product. The training 19 courses they go to. 20 So just -- I'm not going to fault 21 somebody for not regarding the IFU because usually 22 they're inadequate anyway, the way they're written. 23 They're not writing robust IFUs. 24 But each surgeon is going to answer how 25 they learned how to do this -- this course, but --</p>	<p style="text-align: right;">Page 84</p> <p>1 Prolift+M from their surgical training? 2 MR. JONES: Objection. 3 THE WITNESS: No, I don't think so, 4 because these -- these actually came out as 5 procedure kits, and so that wouldn't have been in 6 their medical training. 7 BY MR. GAGE: 8 Q. Have you conducted any study or survey of 9 pelvic floor surgeons who implanted Prolift+M to 10 determine what risks of the device they understood 11 as a result of their medical school education? 12 A. No. 13 Q. What is the role, if any, of medical 14 literature with regard to devices such as the 15 Prolift+M insofar as the pelvic floor surgeons who 16 might implant the device? 17 MR. JONES: Objection. 18 THE WITNESS: The role of medical 19 literature is to impart some knowledge about -- 20 about a particular -- I mean, what is literature in 21 general? I mean, it's to tell you something. 22 But is that where doctors get 23 information about devices? Not always. Usually 24 there's a delay in what comes out in the literature 25 compared to what is being done. It's usually about</p>
<p style="text-align: right;">Page 83</p> <p>1 so, I mean, in terms of medical implanted devices 2 that the IFU has not looked at is not going to 3 necessarily surprise me in the OR. 4 BY MR. GAGE: 5 Q. Have you conducted any study or survey of 6 pelvic floor surgeons to determine whether they read 7 the Prolift+M IFU? 8 A. No. 9 Q. Have you conducted any survey or study of 10 pelvic floor surgeons to determine what risks they 11 understood as a result of reading the Prolift+M IFU? 12 A. Well, I think the Prolift+M IFU is 13 inadequate to begin with. 14 Q. I know. 15 But my specific question is, have you 16 surveyed pelvic floor surgeons to determine what 17 risks they understood as a result of reading the 18 Prolift+M IFU? 19 A. No. 20 Q. Okay. Have you conducted any study or 21 survey of pelvic floor surgeons who implanted 22 Prolift+M to determine what risks of the device they 23 understood as a result of medical school education? 24 A. No, I haven't done that. 25 Q. Could doctors have learned of the risks of</p>	<p style="text-align: right;">Page 85</p> <p>1 five years that you would think about a delay. 2 BY MR. GAGE: 3 Q. Should pelvic floor surgeons implanting 4 Prolift+M read the medical literature about the 5 device before implanting it? 6 A. You know, it's going to be up to the surgeon 7 to talk about it. I can't -- I mean, I'm not going 8 to say a surgeon has to read the medical literature, 9 because for one thing I just said, there's usually a 10 delay. When you introduce new technology, there may 11 not be medical literature. 12 Q. If there is literature, should they read it? 13 A. It depends. I don't know. It depends on 14 the surgeon, what -- how they learn stuff. What 15 they're -- what they're doing. 16 I mean, in terms of a surgical practice, the 17 surgeons don't always have time to read, to go look 18 for the medical literature. Remember, now we've got 19 the Internet, and it wasn't always that easy to find 20 literature. 21 Q. Could doctors have learned of the risks of 22 Prolift+M from their reading of medical literature? 23 A. Probably not. 24 Q. Have you conducted any study or survey of 25 pelvic floor surgeons who implanted Prolift+M to</p>

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<p style="text-align: right;">Page 86</p> <p>1 determine what risks of the device they understood 2 as a result of reading relevant medical literature? 3 A. No. 4 Q. Could doctors have learned of the risks of 5 Prolift+M from their experience implanting other 6 mesh devices? 7 MR. JONES: Objection. 8 THE WITNESS: It depends. I can't give 9 an answer on that. 10 BY MR. GAGE: 11 Q. Have you conducted any study or survey of 12 pelvic floor surgeons who implanted Prolift+M to 13 determine what risks of the device they understood 14 as a result of their experience implanting other 15 mesh devices? 16 A. No. 17 Q. Should doctors have availed themselves of 18 training courses before they implant Prolift+M? 19 MR. JONES: Objection. 20 THE WITNESS: Again, each doctor is 21 going to talk about that. I mean, yes, ideally, but 22 I don't know what their experience is, so I don't 23 know. 24 BY MR. GAGE: 25 Q. Could doctors have learned of the risks of</p>	<p style="text-align: right;">Page 88</p> <p>1 but I don't think reading the patient brochure is 2 going to tell you how to implant the product. 3 Q. Would it tell you anything about the risks 4 of implanting the device? 5 A. Not the patient brochures I reviewed. Most 6 of them, they were all benefits; no risk. 7 Q. Did you review the Prolift+M patient 8 brochure? 9 A. I don't recall if I did or not in terms of I 10 don't remember right now. But since the company 11 wasn't collecting the long-term data, there's -- 12 it's very unlikely there would be any information in 13 it. 14 Q. Have you conducted any study or survey of 15 pelvic floor surgeons who implanted Prolift+M to 16 determine what risks of the device they understood 17 as a result of reading the Prolift+M patient 18 brochure? 19 A. No. 20 Q. And, Dr. Parisian, we talked earlier about 21 the Surgeon's Resource Monograph. 22 A. The training manual, yes, sir. 23 Q. And forgive me, my memory is not as good as 24 it once was. 25 Did you or did you not read it? I'm not</p>
<p style="text-align: right;">Page 87</p> <p>1 Prolift+M from mesh device training courses? 2 A. Probably not since the company wasn't 3 actually giving the information about the potential 4 risks. They weren't updating the physicians as to 5 the risks. 6 Q. Have you conducted any study or survey of 7 pelvic floor surgeons who implanted Prolift+M to 8 determine what risks they understood as a result of 9 participating in training on Prolift+M? 10 A. No. 11 Q. Could doctors have learned of the risks of 12 Prolift+M from Ethicon sponsored surgical training? 13 A. Based on the information I reviewed, no. 14 Q. Have you conducted any study or survey of 15 pelvic floor surgeons who implanted Prolift+M to 16 determine what risks they understood as a result of 17 participating in Ethicon sponsored training on 18 Prolift+M? 19 A. No. 20 Q. Should pelvic floor surgeons implanting 21 Prolift+M read the patient brochure before 22 implanting the device? 23 A. Not necessarily the patient brochure. I 24 mean, the patient brochure is usually what they give 25 out. I mean, it would be -- not be bad for them,</p>	<p style="text-align: right;">Page 89</p> <p>1 trying to ask the same question twice. I just can't 2 remember what your answer was. 3 A. I may have looked at it. Since I'm not a 4 surgeon, I wouldn't have looked at it with great 5 depth. 6 Q. Do you know if you -- do you know if it was 7 a document that was provided to you? 8 A. I don't recall as we sit here today. 9 (Whereupon, Exhibit No. 15 was marked 10 for identification.) 11 MR. GAGE: Okay. Doctor, I'm going to 12 mark as Exhibit No. 15 a document, it begins with 13 ETH.MESH 00658362. It's entitled the "Surgeon's 14 Resource Monograph." 15 And before I hand it to you, I want to 16 let counsel know that I received an e-mail a 17 couple -- a day or two, yesterday I guess, from 18 somebody in my office that said the copy I'm about 19 to mark is missing a few pages at the end. And I 20 had already left and didn't have time to get a 21 better copy. 22 So I'm not going to ask Dr. Parisian 23 about the specifics. I recognize I'm missing a few 24 pages here, but I would ask permission of counsel 25 for me to substitute the correct copy.</p>

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<p style="text-align: right;">Page 90</p> <p>1 I don't think it's -- I don't think the 2 fact that there's some pages missing at the end are 3 going to impact at all my questioning of the 4 witness. 5 MR. AYLSTOCK: Yeah. Can you just 6 identify which pages or -- 7 MR. GAGE: I don't know. He just meant 8 me -- my guy in my office sent me an e-mail and 9 said, "Hey, I want you to know, that is the correct 10 document, but I looked at it, and, apparently, we've 11 got one -- there apparently are a couple pages 12 missing near the end." 13 And I had already made copies and flown 14 out here, so my request would be that we substitute 15 the complete and full copy. I'm not going to ask 16 the witness about the specifics of it such that the 17 missing pages would impact. 18 MR. JONES: Sure. I mean, do you have 19 a copy? 20 MR. GAGE: Yeah. And so there's a copy 21 for the witness, and there's a copy for counsel, 22 obviously. 23 BY MR. GAGE: 24 Q. Dr. Parisian, I just want to know, is this a 25 document that is familiar to you, recognizing that I</p>	<p style="text-align: right;">Page 92</p> <p>1 A. Probably so if it's not on my list. 2 Q. All right. So, Doctor, I'm going to ask you 3 a question, but if you have not seen the document, I 4 don't believe you're going to be able to answer the 5 question, but I'll ask it just to make sure. 6 Could doctors -- could doctors have learned 7 of the risks of Prolift+M from reading the Surgeon's 8 Resource Monograph? 9 And I suspect your answer will be -- well, 10 let me strike that. Let me just -- let me re-ask 11 it. 12 MR. AYLSTOCK: Okay. 13 BY MR. GAGE: 14 Q. Doctor, could doctors have learned of the 15 risks of Prolift+M from reading the Surgeon's 16 Resource Monograph? 17 MR. AYLSTOCK: And just for the record, 18 there's no date here, and it's Prolift -- it's not 19 the Prolift+M -- document just so the record is 20 clear. 21 THE WITNESS: Right. So this is 22 Prolift. 23 Well, it has a lot of questions because 24 we don't know when a person took a course. We don't 25 know what this one is. And it's Prolift, as opposed</p>
<p style="text-align: right;">Page 91</p> <p>1 have been told that some pages are missing, a 2 couple -- at least a couple of pages are missing 3 near the end? 4 A. I don't -- I don't recall. I've looked 5 at -- I don't recall. 6 Q. Does it look -- 7 A. What's the date of this one anyway? This 8 is -- I can't read the -- 9 Q. I don't have a specific date for you. 10 It's -- 11 A. I can't read the -- all right. 12 MR. AYLSTOCK: It's sort of -- the copy 13 is not very good. 14 MR. GAGE: Is there a copy review date 15 at the back? 16 MR. AYLSTOCK: There's something, but 17 it's very faint. I don't know. 18 THE WITNESS: So what's your question? 19 BY MR. GAGE: 20 Q. Well, my question is, is this document 21 familiar to you? 22 A. I don't remember. 23 Q. And if it's not on your reliance list, is 24 it -- is it correct to say that you've never seen 25 it?</p>	<p style="text-align: right;">Page 93</p> <p>1 to Prolift+M. And there's nothing about postmarket, 2 these are the rates that we have. 3 BY MR. GAGE: 4 Q. I'll tell you what. I will withdraw the 5 question because the witness has not reviewed -- 6 A. Thank you. 7 Q. Doctor, just to summarize, that document is 8 not familiar to you as you sit here today? 9 A. Correct. 10 Q. And it is correct to say that if that 11 document does not appear on your reliance list which 12 we've marked as an exhibit, then it would be a true 13 statement that today is the first day you've seen 14 that document? 15 A. Yes, sir. 16 Q. Okay. 17 THE WITNESS: May I go to the bathroom 18 really quick? 19 MR. GAGE: Absolutely. 20 THE WITNESS: All right. Be right 21 back. 22 (Recess taken.) 23 (Whereupon, Exhibit No. 16 was marked 24 for identification.) 25 ///</p>

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<p style="text-align: right;">Page 94</p> <p>1 BY MR. GAGE:</p> <p>2 Q. Dr. Parisian, I'm going to hand you a</p> <p>3 composite Exhibit 16, which contains, as I counted,</p> <p>4 11 different pieces of medical literature regarding</p> <p>5 Prolift+M.</p> <p>6 Could you just spend a few seconds looking</p> <p>7 through that and just generally familiarizing</p> <p>8 yourself with those documents?</p> <p>9 A. Okay.</p> <p>10 Q. Dr. Parisian, my question -- well, I'll make</p> <p>11 a statement, and then I'll ask a question.</p> <p>12 I will represent to you that I had someone</p> <p>13 in my office look over your reliance list, and I've</p> <p>14 been advised by someone in my office that these</p> <p>15 pieces of medical literature regarding Prolift+M do</p> <p>16 not appear on your reliance list.</p> <p>17 And my question to you is, are any of those</p> <p>18 pieces of medical literature familiar to you?</p> <p>19 MR. JONES: Objection. I don't think</p> <p>20 that's a completely accurate characterization, but</p> <p>21 it's just an objection for the record.</p> <p>22 MR. GAGE: It may not be. I was told</p> <p>23 they couldn't find them on there, and so I didn't go</p> <p>24 back and double-check, but I asked them to</p> <p>25 double-check, but I could be --</p>	<p style="text-align: right;">Page 96</p> <p>1 A. I don't know.</p> <p>2 Q. I'm talking about for you.</p> <p>3 A. For me?</p> <p>4 Q. Yes.</p> <p>5 A. I do my own literature searches. What do</p> <p>6 you mean? In terms of --</p> <p>7 Q. I'm sorry. I misunderstood.</p> <p>8 I thought you just said a few minutes ago or</p> <p>9 just a second ago something that would suggest that</p> <p>10 you had someone else doing --</p> <p>11 A. No.</p> <p>12 Q. -- the literature searches for you.</p> <p>13 A. No, no, no, no, because, I mean, I've looked</p> <p>14 at all kinds of mesh.</p> <p>15 And so if I look at this document, would</p> <p>16 there be some things that I've seen before, and yes,</p> <p>17 I have. Did I do an ultimate literature search in</p> <p>18 my report for Prolift+M? No, I didn't do that. I</p> <p>19 don't even list that. But, you know, there are some</p> <p>20 articles I've seen, some articles I haven't seen.</p> <p>21 Q. All right. Let me ask you this: Did you</p> <p>22 read any of the articles in Exhibit 16 for purposes</p> <p>23 of drafting your Prolift+M report?</p> <p>24 MR. JONES: Objection.</p> <p>25 THE WITNESS: I don't recall that I</p>
<p style="text-align: right;">Page 95</p> <p>1 MR. JONES: I think it just has to do</p> <p>2 with the data and then how it gets published, and I</p> <p>3 would say a lot of the underlying data is discussed</p> <p>4 actually in the body of the report and in these</p> <p>5 articles.</p> <p>6 THE WITNESS: Some of them are, like I</p> <p>7 know the Taiwan study looking at the mesh versus</p> <p>8 the web, so some of them are but not all of them.</p> <p>9 BY MR. GAGE:</p> <p>10 Q. Do you know why -- assuming I'm correct</p> <p>11 about this, do you know why they would not be --</p> <p>12 those that are familiar to you would not be</p> <p>13 specifically listed on your reliance list?</p> <p>14 MR. JONES: Objection.</p> <p>15 THE WITNESS: It's because I've looked</p> <p>16 at a lot of different mesh studies, and so I -- from</p> <p>17 a lot of different companies, so I might have seen</p> <p>18 them.</p> <p>19 I'm not the person who's doing like the</p> <p>20 ultimate literature search and the -- I'm looking at</p> <p>21 it from what would have been known and knowable and</p> <p>22 information but not the person who is an expert in</p> <p>23 urological treatment of prolapse.</p> <p>24 BY MR. GAGE:</p> <p>25 Q. Who is doing the literature searches?</p>	<p style="text-align: right;">Page 97</p> <p>1 did, but some of those are things that I've seen, so</p> <p>2 I don't think so, and I don't think I referenced</p> <p>3 them particularly, but they're in my head in that</p> <p>4 I've seen these articles before.</p> <p>5 BY MR. GAGE:</p> <p>6 Q. Okay.</p> <p>7 A. Does that answer your question?</p> <p>8 Q. Yes. I think -- and I don't want to be</p> <p>9 unfair to you, so listen carefully.</p> <p>10 I think what you're telling me is it's</p> <p>11 possible that you have seen one or more of these</p> <p>12 articles in Exhibit 16 through the course of your</p> <p>13 time working as an expert in the mesh litigation?</p> <p>14 A. Right.</p> <p>15 Q. But for purposes of drafting your Prolift+M</p> <p>16 report, you did not specifically review these</p> <p>17 articles for purposes of drafting that report?</p> <p>18 A. Right.</p> <p>19 And if you notice in my Prolift+M, there's</p> <p>20 no section that says the medical literature for</p> <p>21 Prolift+M.</p> <p>22 Q. Why is that?</p> <p>23 A. Because I didn't do that, and sometimes --</p> <p>24 some reports that I do, but in this particular</p> <p>25 case -- I mean, it actually had a very short</p>

25 (Pages 94 to 97)

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<p style="text-align: right;">Page 98</p> <p>1 lifespan, and I focused more in my report on the 2 510(k) and the marketing information because we had 3 the Prolift and the Prolift+M, so you're actually 4 having two products in the one report. 5 Q. Is there some specific reason why you did 6 not include a section in your report about the 7 published medical literature on Prolift+M? 8 A. I just didn't do it. I mean, some reports I 9 do. I didn't do it on TVT-Secur either, but 10 sometimes I would, and then I would list them, but I 11 didn't list them. 12 Q. Was that your decision? 13 A. It wasn't anybody's conscious decision. 14 It's just not in the report. 15 Q. I see. 16 It wasn't that you made a conscious decision 17 not to do it; it's simply that you didn't make a 18 conscious decision to do it? 19 A. That's right. Because I felt like there 20 were more people who were talking about the urology, 21 the treatment of patients, and I didn't see that as 22 my role. 23 Q. Dr. Parisian, you are aware that there are 24 various surgical procedures to repair pelvic organ 25 prolapse that don't involve the use of mesh;</p>	<p style="text-align: right;">Page 100</p> <p>1 Q. Is chronic dyspareunia a risk of a non-mesh 2 surgery to POP? 3 A. I don't know that it -- 4 Q. POP -- when I say "POP," you understand what 5 I mean, pelvic organ prolapse, P-O-P? 6 A. Yeah, pelvic organ prolapse. 7 Q. Okay. So let me rephrase the question. 8 Is chronic dyspareunia a risk of a non-mesh 9 surgery to treat POP? 10 MR. JONES: Objection. 11 THE WITNESS: And I would say I don't 12 know. Because when they used to do non-risk -- 13 non-mesh surgery, those patients were usually 14 chronic patients to begin with. They didn't -- 15 what's new is that we have the -- the POP procedures 16 with the mesh being done on women who were healthy 17 and had no problems. 18 So that you have to look at the 19 pre-transvaginal mesh surgery as these are patients 20 who are chronic that went to surgery, so I don't 21 know. 22 So, again, it would be a urologist 23 talking about that, but this would be, for our 24 transvaginal mesh, could have chronic dyspareunia in 25 a woman that was -- didn't have it to begin with,</p>
<p style="text-align: right;">Page 99</p> <p>1 correct? 2 A. Right. Those are your traditional ones for 3 the urology group. 4 Q. Do you know what the risks of those non-mesh 5 pelvic organ prolapse surgeries are? 6 A. No, not offhand. 7 Q. I'll ask you some and then -- I'll ask you 8 about some of the risks, and I'll ask you to let me 9 know whether you believe it's a risk or not. 10 So the first question is, is pain with 11 intercourse a potential risk of a non-mesh pelvic 12 organ prolapse surgery? 13 A. It can be, but when are you talking about 14 the pain? Dyspareunia, that would be -- because 15 typically when you think of dyspareunia in those 16 patients, it's usually acute. It's not something 17 that's chronic. 18 In our cases, the women -- and I'm not going 19 to be talking about this in terms of the symptoms, I 20 don't believe. Am I? 21 But in terms of dyspareunia, the thing that 22 was unusual here is that it's chronic, it's 23 prolonged, and it can be dyspareunia for a woman and 24 also for her partner in that they can actually feel 25 the mesh.</p>	<p style="text-align: right;">Page 101</p> <p>1 whereas they may have had it with the other surgery. 2 BY MR. GAGE: 3 Q. What we would call de novo dyspareunia? 4 A. Yeah. 5 Q. Okay. Is de novo chronic dyspareunia a risk 6 of a non-mesh surgery to treat POP? 7 A. I don't know because I'm saying with the 8 caveat that those patients who got treated 9 surgically before, like with the Burch or Marchetti, 10 those types of procedures, they -- they actually had 11 a whole bunch of symptoms before their procedure. 12 So I don't know if it was -- de novo was new for 13 those procedures. 14 Q. Is chronic dyspareunia a risk of a Prolift+M 15 surgery? 16 A. Yeah. 17 Q. Is -- does the fact that Prolift+M carries 18 with it the risk of chronic dyspareunia mean that 19 the device is defectively designed? 20 A. You know, I don't think I've seen a good 21 reason for what the dyspareunia is coming from, so I 22 think that would be others who would talk about 23 that. 24 Q. All right. 25 A. Because you could have dyspareunia for many</p>

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<p style="text-align: right;">Page 102</p> <p>1 different factors, so it could be the overall 2 design, surgical. I don't think that's necessarily 3 what I'm talking about in terms of litigation. 4 Q. Is chronic pain a general risk of a non-mesh 5 surgery to treat pelvic organ prolapse? 6 MR. JONES: Objection. 7 THE WITNESS: Well, you know, I'm going 8 to fall back on the FDA saying that they were 9 looking at the non-TVM risks, and they were saying 10 that the risks were unique compared to the risks for 11 the surgical procedures. 12 So the FDA has made that the risks are 13 unique and different for these TVM procedures 14 compared to the traditional surgical procedures. 15 And that's actually what they're going 16 to be doing the PMAs for, to find out that answer, 17 so I can't answer it. That's what the FDA is trying 18 to get data for. 19 BY MR. GAGE: 20 Q. So my question -- I think my question is, is 21 chronic pain a risk of a non-mesh surgery to treat 22 pelvic organ prolapse? 23 That's my simple question. 24 MR. JONES: Objection. 25 THE WITNESS: And I would say I don't</p>	<p style="text-align: right;">Page 104</p> <p>1 what the procedure is, I can't answer that. That's 2 what the FDA is trying to get them to answer. 3 Q. Is organ or nerve damage a risk of a 4 non-mesh surgery to treat pelvic organ prolapse? 5 A. It can be. 6 Q. Is bleeding a risk of a non-mesh surgery to 7 treat pelvic organ prolapse? 8 A. Well, bleeding is always a risk of a 9 surgery. The question is not is it a risk. The 10 issue is, is it worse? For a woman that was fairly 11 stable to begin with is it worse than would be 12 anticipated if she had gone with a traditional 13 procedure? 14 So you're talking apples and oranges. The 15 traditional procedures were people who were in bad 16 states to begin with. 17 Q. I understand that. I'm not really doing the 18 comparison right now. I'm just simply asking 19 whether these risks are risks of non-mesh surgeries 20 to treat pelvic organ prolapse. 21 I have not yet gone to the next question 22 about comparing those non-mesh surgeries to mesh 23 surgeries. 24 A. Okay. 25 Q. So are wound complications a risk of a</p>
<p style="text-align: right;">Page 103</p> <p>1 know, and there's going to be more information -- 2 that's what the FDA wants to know. Was chronic pain 3 for the traditional surgical procedure, is it worse 4 now for the TVM procedures? They're trying to 5 quantify that. 6 BY MR. GAGE: 7 Q. Is vaginal scarring a risk of a non-mesh 8 surgery to treat pelvic organ prolapse? 9 MR. JONES: Objection. 10 THE WITNESS: I don't -- I don't know. 11 And vaginal scarring I don't think was -- but, 12 again, this would be a different -- this is apple 13 and oranges in terms of the patient, so I don't 14 know. 15 BY MR. GAGE: 16 Q. Is injection a risk of a non-mesh surgery to 17 treat pelvic organ prolapse? 18 A. Infection is a risk for any kind of surgery, 19 but the issue is that the mesh makes it much more 20 difficult to treat the infection. 21 Q. Are urinary problems, including urinary 22 frequency, retention, obstruction, urge 23 incontinence, and voiding dysfunction a risk of a 24 non-mesh surgery to treat pelvic organ prolapse? 25 A. I don't know. In terms of who the woman is,</p>	<p style="text-align: right;">Page 105</p> <p>1 non-mesh surgery to treat pelvic organ prolapse? 2 MR. JONES: Objection. 3 THE WITNESS: Yes. It can be. A wound 4 complication, yes. 5 BY MR. GAGE: 6 Q. Is inflammation a risk of a non-mesh surgery 7 to treat pelvic organ prolapse? 8 MR. JONES: Objection. 9 THE WITNESS: It can be. Any surgery 10 can have inflammation risks. 11 BY MR. GAGE: 12 Q. Is fistula formation a risk of a non-mesh 13 surgery to treat pelvic organ prolapse? 14 MR. JONES: Objection. 15 THE WITNESS: It can be. 16 BY MR. GAGE: 17 Q. Are neuromuscular problems a risk of a 18 non-mesh surgery to treat pelvic organ prolapse? 19 A. It can be. 20 Q. Is there a risk that one or more surgeries 21 may be needed to treat an adverse event arising out 22 of a non-mesh surgery to treat pelvic organ 23 prolapse? 24 MR. JONES: Objection. 25 THE WITNESS: Yes.</p>

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<p style="text-align: right;">Page 106</p> <p>1 BY MR. GAGE:</p> <p>2 Q. Is a manufacturer of a surgically implanted</p> <p>3 medical device required to warn surgeons of the</p> <p>4 general risks of surgery or of only those specific</p> <p>5 and unique to the device itself?</p> <p>6 A. Both.</p> <p>7 They're supposed to provide adequate</p> <p>8 instructions and adequate warnings. So there can be</p> <p>9 general surgical risks, yes, but you have to make</p> <p>10 the -- the information so that the physician would</p> <p>11 know, in terms of your device, what are the</p> <p>12 potential risks and benefits so they can make an</p> <p>13 informed decision.</p> <p>14 Q. If a risk is common to both a mesh surgery</p> <p>15 and a non-mesh surgery, must -- must the</p> <p>16 manufacturer of a medical device making that mesh</p> <p>17 include that risk in the IFU or the patient</p> <p>18 brochure?</p> <p>19 A. Yes, because as I've been trying to say,</p> <p>20 there's two different populations. The woman who</p> <p>21 went through the traditional, non-mesh surgery was a</p> <p>22 different population than this woman that would have</p> <p>23 a 15-minute office procedure, and they usually had</p> <p>24 minor symptoms.</p> <p>25 So in terms of the risk versus benefit, a</p>	<p style="text-align: right;">Page 108</p> <p>1 But you, as the manufacturer Ethicon,</p> <p>2 have to have a postmarket surveillance group that's</p> <p>3 determining what your risks are specific for your</p> <p>4 device to put in your label.</p> <p>5 And so that's what's missing is, yes,</p> <p>6 there are some generic terms that people have put in</p> <p>7 for mesh, but what's missing from the label is, how</p> <p>8 does Prolift work in terms of a patient? How does</p> <p>9 Prolift+M work in terms of a patient? A physician</p> <p>10 can decide whether to implant it.</p> <p>11 BY MR. GAGE:</p> <p>12 Q. Is foreign body response a risk of a</p> <p>13 non-mesh surgery to treat pelvic organ prolapse?</p> <p>14 MR. JONES: Objection.</p> <p>15 THE WITNESS: You can have foreign body</p> <p>16 response -- I mean, it's a very generic name, so</p> <p>17 what are you talking about, "foreign body response"?</p> <p>18 BY MR. GAGE:</p> <p>19 Q. Do you know what foreign body response is?</p> <p>20 A. Sure, I know what it is, but what do you</p> <p>21 want? Because a foreign body response, you can</p> <p>22 have -- like a suture can cause a foreign body</p> <p>23 response. And a lot of times sutures will get</p> <p>24 expelled. That's a foreign body response. Or you</p> <p>25 can have the mesh, which is a foreign body, causing</p>
<p style="text-align: right;">Page 107</p> <p>1 woman who's had a bad outcome and problems would be</p> <p>2 able to accept different risk versus benefit than a</p> <p>3 woman who has really insignificant issues.</p> <p>4 And so you have to as a manufacturer give</p> <p>5 adequate information to the doctor to make a risk</p> <p>6 versus benefit determination.</p> <p>7 You're taking a woman that's almost healthy</p> <p>8 and giving her an elective procedure. The benefits</p> <p>9 are not that great, so your risks have to be</p> <p>10 commiserate with that type of a procedure.</p> <p>11 So, yes, the manufacturer is required to</p> <p>12 provide that literature in their label.</p> <p>13 Q. And just so that we're clear, that</p> <p>14 information -- when you use the phrase "that</p> <p>15 information," you include within that not only the</p> <p>16 risks that are unique to mesh devices, such as the</p> <p>17 risk of erosion, but also every risk that could</p> <p>18 potentially occur even if that risk was not unique</p> <p>19 to that particular device?</p> <p>20 MR. JONES: Objection.</p> <p>21 THE WITNESS: What you've forgotten is</p> <p>22 that you got to put the risk for your device in</p> <p>23 there. You haven't said that. You said that we</p> <p>24 would have, you know, general risks that -- for</p> <p>25 surgery, yes, okay.</p>	<p style="text-align: right;">Page 109</p> <p>1 it. So what foreign body response are we talking</p> <p>2 about?</p> <p>3 Q. Well, I think my question was, is foreign</p> <p>4 body response a risk of a non-mesh surgery that uses</p> <p>5 any foreign body to treat pelvic organ prolapse?</p> <p>6 A. It can be, but the company has to provide a</p> <p>7 description. What's the likelihood of having a</p> <p>8 foreign body response with Prolift+M?</p> <p>9 I mean, we're talking about Prolift+M. That</p> <p>10 information needs to be in the label. So you don't</p> <p>11 say it's minor. How big of a foreign body response</p> <p>12 are we talking about?</p> <p>13 Q. Are surgeons taught about foreign body</p> <p>14 response in medical school?</p> <p>15 MR. JONES: Objection.</p> <p>16 THE WITNESS: In a generic fashion,</p> <p>17 yeah. Foreign body response is a known term that</p> <p>18 surgeons would know about. The thing is --</p> <p>19 BY MR. GAGE:</p> <p>20 Q. What are they taught?</p> <p>21 A. What are they taught? I mean, I think if</p> <p>22 you're talking about most surgeons, I mean, a</p> <p>23 foreign body response would mean there's a risk</p> <p>24 of -- that's why a lot of surgeons don't want to put</p> <p>25 any foreign materials in a human because people will</p>

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<p style="text-align: right;">Page 110</p> <p>1 respond to the foreign materials. 2 But the question is the degree of foreign 3 body response that we would have for Prolift+M. 4 Q. All right. And my question is, what are 5 surgeons taught? 6 MR. JONES: Objection. 7 THE WITNESS: Well, I mean, I can't 8 talk for all surgeons, but I know that for foreign 9 body response is -- from a surgeon's point of view, 10 it's a foreign body. So suture can cause it. 11 Anything that's a foreign body can cause a foreign 12 body response. 13 BY MR. GAGE: 14 Q. How long can that foreign body response 15 persist? 16 MR. JONES: Objection. 17 THE WITNESS: It depends on the foreign 18 body response. It can persist. Like if you leave a 19 sponge in somebody, that will create a foreign body 20 response and eventually will manifest with an 21 infection or something that might trigger it to come 22 out. 23 So it's just -- it's a big spectrum, 24 foreign body response, so I don't think I can answer 25 it any other way.</p>	<p style="text-align: right;">Page 112</p> <p>1 BY MR. GAGE: 2 Q. Was the risk of chronic dyspareunia with 3 mesh devices known to the medical community in 2008? 4 MR. JONES: Objection. 5 THE WITNESS: I don't -- I think that 6 the medical community's going to have to talk about 7 it in terms of the FDA didn't make it sound like 8 they were in terms of their public health 9 notification. 10 BY MR. GAGE: 11 Q. Well, I'm -- 12 A. I mean, chronic dyspareunia is -- chronic 13 dyspareunia is a significant problem with a device. 14 Q. Dr. Parisian, I'm very specific, just asking 15 you this question: Was chronic dyspareunia with 16 mesh devices known to the medical community in 2008? 17 MR. JONES: Objection. 18 THE WITNESS: I don't know. I can't 19 talk for every -- I mean, again, it would be the 20 physician that's caring for the patient. 21 BY MR. GAGE: 22 Q. Was the risk of chronic pain with mesh 23 devices known to the medical community in 2008? 24 MR. JONES: Objection. 25 THE WITNESS: I can't speak for what</p>
<p style="text-align: right;">Page 111</p> <p>1 BY MR. GAGE: 2 Q. But is that something that's taught to 3 surgeons in medical school or during their training? 4 MR. JONES: Objection. 5 THE WITNESS: You know, we're talking 6 about the degrees. I mean, because pathologists, 7 we're sitting there describing foreign body 8 responses, and so we are very meticulous. We look 9 at it, whether it's chronic, whether it's acute, you 10 know, the cell type, and all that stuff. 11 Surgeons just tend to think it's a 12 foreign body, you can have a foreign body response. 13 So there's all kinds of gradations of foreign body 14 response. 15 So, yeah, I think everybody who goes to 16 medical school knows you can have a foreign body 17 response, but you need to tell them what kind of 18 foreign body response you're going to have, and is 19 it going to be severe foreign body response? 20 So it's the two words, foreign body 21 response -- three words, yes, they know those words. 22 But you have to -- as in adequate instructions and 23 warnings, you have to tell them what is to be 24 anticipated for this product. 25 ///</p>	<p style="text-align: right;">Page 113</p> <p>1 the medical community knows. 2 BY MR. GAGE: 3 Q. Was the risk of vaginal scarring with mesh 4 devices known to the medical community in 2008? 5 MR. JONES: Objection. 6 THE WITNESS: You know, I can't speak 7 for the whole medical community. I don't think so. 8 BY MR. GAGE: 9 Q. Was the risk of urinary problems with mesh 10 devices known to the medical community in 2008? 11 MR. JONES: Objection. 12 THE WITNESS: Well, you're talking 13 about general. You're not talking about Prolift+M? 14 BY MR. GAGE: 15 Q. Correct. 16 A. You're just talking general. I don't know. 17 Q. Was the risk of organ and nerve damage with 18 mesh devices known to the medical community in 2008? 19 A. I don't know. 20 Q. Was the risk of bleeding and wound 21 complications with mesh devices known to the medical 22 community in 2008? 23 A. Again, I can't answer that. I mean, these 24 are complications of surgery, but whether an 25 individual surgeon who was putting this in knew</p>

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<p style="text-align: right;">Page 114</p> <p>1 that, I can't answer that.</p> <p>2 Q. Was the risk of inflammation with mesh</p> <p>3 devices known to the medical community in 2008?</p> <p>4 MR. JONES: Objection.</p> <p>5 THE WITNESS: I can't answer it.</p> <p>6 BY MR. GAGE:</p> <p>7 Q. Was the risk of fistula formation known to</p> <p>8 the medical community -- I'm sorry. Strike that.</p> <p>9 Was the risk of fistula formation with mesh</p> <p>10 devices known to the medical community in 2008?</p> <p>11 A. I don't -- I don't know if it was or not,</p> <p>12 and that was part of the issue that the FDA came out</p> <p>13 with that public health notification is that they</p> <p>14 were concerned that people weren't aware of the</p> <p>15 risks.</p> <p>16 Q. Was the risk of neuromuscular problems with</p> <p>17 mesh devices known to the medical community in 2008?</p> <p>18 MR. JONES: Same objection.</p> <p>19 THE WITNESS: I don't know. Same</p> <p>20 answer.</p> <p>21 BY MR. GAGE:</p> <p>22 Q. Was the risk that a surgery involving a mesh</p> <p>23 device might necessitate one or more surgeries to</p> <p>24 treat an adverse event known to the medical</p> <p>25 community in 2008?</p>	<p style="text-align: right;">Page 116</p> <p>1 Is that what your understanding is?</p> <p>2 A. Yeah. Yes, sir.</p> <p>3 Q. You don't need to call me "sir."</p> <p>4 Have you reviewed this document in</p> <p>5 preparation for your report?</p> <p>6 A. I don't -- I don't recall that I have.</p> <p>7 Q. Do you recall whether you looked at the</p> <p>8 Prolift+M patient brochure?</p> <p>9 A. I don't recall what I looked at as we sit</p> <p>10 here.</p> <p>11 Q. All right. I just got a few questions about</p> <p>12 the -- about the IFU.</p> <p>13 Can you see on the second page, about four</p> <p>14 lines down, it says, "The safety" -- do you see the</p> <p>15 paragraph beginning with, "The safety and</p> <p>16 effectiveness"? Do you see that?</p> <p>17 A. Where are you? Oh, okay. Yes, sir.</p> <p>18 Q. Okay. So I'm going to read just a sentence</p> <p>19 there and ask you a question about it.</p> <p>20 It says, "The safety and effectiveness of</p> <p>21 the Gynecare Prolift+M systems compared to</p> <p>22 conventional surgical repair for pelvic organ</p> <p>23 prolapse have not been demonstrated in randomized</p> <p>24 clinical trials."</p> <p>25 Do you see that?</p>
<p style="text-align: right;">Page 115</p> <p>1 MR. JONES: Objection.</p> <p>2 THE WITNESS: I don't think so, and I</p> <p>3 can't answer for the medical community. That was</p> <p>4 why the FDA was asking for that information.</p> <p>5 BY MR. GAGE:</p> <p>6 Q. Was the risk of erosion, exposure, extrusion</p> <p>7 with mesh devices known to the medical community in</p> <p>8 2008?</p> <p>9 A. Again, I can't answer that.</p> <p>10 Q. Was the risk of contraction or shrinkage of</p> <p>11 the mesh known to the medical community in 2008?</p> <p>12 MR. JONES: Objection.</p> <p>13 THE WITNESS: Same answer.</p> <p>14 BY MR. GAGE:</p> <p>15 Q. Dr. Parisian, with regard -- let me -- well,</p> <p>16 strike that.</p> <p>17 (Whereupon, Exhibit No. 17 was marked</p> <p>18 for identification.)</p> <p>19 BY MR. GAGE:</p> <p>20 Q. Dr. Parisian, I'm going to hand you</p> <p>21 Exhibit 17. Do you know what that is?</p> <p>22 A. It looks like the labeling for the</p> <p>23 Prolift+M.</p> <p>24 Q. And I've often referred to it as the IFU,</p> <p>25 instructions for use.</p>	<p style="text-align: right;">Page 117</p> <p>1 A. Yes, sir.</p> <p>2 Q. What does that communicate to a surgeon who</p> <p>3 reads that sentence?</p> <p>4 A. That there haven't been -- this is something</p> <p>5 FDA requested, that there haven't been clinical</p> <p>6 trials for -- to look at the Prolift+M system.</p> <p>7 Q. All right. And then two -- skip a sentence,</p> <p>8 and let's go to the next sentence that reads,</p> <p>9 "Information on." Do you see that, in the same</p> <p>10 paragraph? Actually, it's the next to last sentence</p> <p>11 in that paragraph.</p> <p>12 A. Yes.</p> <p>13 This is -- this is -- I remember this. This</p> <p>14 is the -- the thing that the FDA and the company</p> <p>15 debated on. The FDA just wanted it to be that first</p> <p>16 line all along about there had been no randomized</p> <p>17 control or trials, and then they negotiated at the</p> <p>18 last minute that they would have this information.</p> <p>19 You skipped the part about the bench testing and</p> <p>20 cadaver testing.</p> <p>21 Q. Yes.</p> <p>22 A. And the company asked for that, that they</p> <p>23 wanted to have that there's -- so that implies that</p> <p>24 there actually has been some testing, which isn't</p> <p>25 what the FDA had wanted.</p>

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<p style="text-align: right;">Page 118</p> <p>1 And then they have, "The information is 2 available in the public literature." The FDA wanted 3 them to put in some references to certain articles, 4 and they said that -- Ethicon said we wanted to put 5 in that we want you to contact our company sales 6 representative for assistance. 7 So this was -- this is discussed in my 8 report is that negotiated statement that was between 9 FDA and the company. 10 Q. Is it a good thing that the -- that the 11 first sentence appears in the IFU? 12 A. Yeah. That was the line the FDA asked for, 13 because they -- they were concerned. 14 Q. Do you agree that it should have been 15 included? 16 A. Yeah. I think it should have been included 17 all by itself and not the other stuff that they put 18 in about the cadaver testing and the bench testing. 19 That was what the company threw in. I think 20 it would have been much more robust just to have 21 that one line that there's no -- there's no data. 22 There was no data supposedly for this product, which 23 is what FDA was trying to give the physician. 24 Q. All right. So the sentence -- you see the 25 sentence beginning with, "Information on"?</p>	<p style="text-align: right;">Page 120</p> <p>1 mesh for pelvic floor repair is available in 2 published literature," is that a true statement? 3 A. Yeah, but it really has nothing to do with 4 Prolift+M, so it watered down what FDA was asking 5 for, a statement that there is no information on 6 this stuff, surgeon, so surgeon beware. 7 And instead the company put a much more 8 user-friendly statement in there because the mesh 9 has nothing to do with Prolift+M. I mean, there's a 10 lot of mesh literature but nothing about Prolift+M. 11 Q. Is it your opinion that the -- that the 12 entirety of the mesh literature that preceded 13 Prolift+M is not relevant to Prolift+M? 14 MR. JONES: Objection. 15 THE WITNESS: Not for a surgeon. I 16 mean, the surgeon is trying to figure out, should I 17 use this versus somebody else's thing? Should I use 18 the traditional? 19 So in terms of this information, it's 20 misleading. It's making it sound like there is no 21 information, but we have mesh information that you 22 can look at, so you've watered it down. 23 And so it's unfortunate, and I talk 24 about it in terms of the negotiation. It watered it 25 down and made it a much more marketing friendly</p>
<p style="text-align: right;">Page 119</p> <p>1 A. Yes, sir. 2 Q. Okay. It says, "Information on the clinical 3 performance of mesh for pelvic organ repair is 4 available in published literature." 5 Do you see that? 6 A. Yes, sir. 7 Q. What does that communicate to a surgeon who 8 is reading that sentence? 9 A. It sounds like there's actually clinical 10 performance information about this device, and 11 that's not true, and then contact your sales 12 representative. 13 The first line is the important line. 14 There's been no study. And so then when you start 15 getting down in this statement where there's been 16 bench testing and cadaver testing, there really 17 hadn't been, and then the information, go talk to 18 your sales rep, so that's basically a sales 19 promotional-type thing. And this was negotiated at 20 the last minute with the FDA. 21 Q. Is it -- okay. So the sentence that says, 22 "Information on the clinical performance of mesh for 23 pelvic floor repair," is that a true statement? 24 I'm sorry. Let me strike that. 25 "Information on the clinical performance of</p>	<p style="text-align: right;">Page 121</p> <p>1 statement to say there's no information. The other 2 mesh literature has nothing to do with Prolift+M, 3 and so it's misleading to even put it there. 4 BY MR. GAGE: 5 Q. What about the literature on Prolift? Would 6 it have any relevance? 7 A. Not necessarily because this is Prolift+M, 8 and FDA said they wanted the two to be clearly 9 separate in terms of information. 10 Q. Let me ask you this: When a device 11 manufacturer submits a 510(k) to the FDA for a 12 device, is it inappropriate for the company to point 13 to medical literature that relates to a product or 14 device? 15 A. No, but Prolift is not the predicate. I 16 mean the -- 17 Q. That wasn't my question. 18 A. No. 19 Q. My question doesn't have anything to do with 20 Prolift or Prolift+M. 21 When a device manufacturer submits a 22 510(k) -- 23 A. Right. 24 Q. -- to the FDA, is it ever appropriate for 25 the manufacturer to cite to medical literature that</p>

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<p style="text-align: right;">Page 122</p> <p>1 pertains to the predicate?</p> <p>2 A. Yes.</p> <p>3 Q. Why?</p> <p>4 A. Because the reviewer has to have a</p> <p>5 background of the summary of the safety information.</p> <p>6 And if there's relevant information in the medical</p> <p>7 literature, that should be given to the FDA reviewer</p> <p>8 so they can consider whether they -- there are new</p> <p>9 issues of safety and effectiveness, if they need to</p> <p>10 ask for testing information.</p> <p>11 And so, yeah, that makes -- that would be</p> <p>12 logical to give that to the FDA. In fact, you're</p> <p>13 required to do that in terms of no material fact not</p> <p>14 provided to the FDA.</p> <p>15 Q. All right. But as I understand it, that</p> <p>16 same analysis is not appropriate in the context of</p> <p>17 an IFU for a medical device?</p> <p>18 MR. JONES: Objection.</p> <p>19 THE WITNESS: No, that's not what I'm</p> <p>20 saying.</p> <p>21 In this particular case, the FDA had</p> <p>22 wanted that line that there was no information of</p> <p>23 Prolift+M, that it concerned the FDA. And then the</p> <p>24 company said, no, we're going to -- and they</p> <p>25 negotiated this other statement, which waters down</p>	<p style="text-align: right;">Page 124</p> <p>1 implanting Prolift+M?</p> <p>2 A. Not necessarily. They don't have time to do</p> <p>3 that. Surgeons are fairly busy, and they rely on</p> <p>4 the sales reps to give them the important</p> <p>5 information, which is what it says here, "Contact</p> <p>6 your sales rep."</p> <p>7 But I think it's just -- it's a gratuitous</p> <p>8 statement to say, yeah, there's pelvic mesh</p> <p>9 literature. It has nothing to do with Prolift+M.</p> <p>10 Q. So in the context of Prolift+M, when the</p> <p>11 device first comes on the market, it's your opinion</p> <p>12 there was no published literature regarding its</p> <p>13 performance?</p> <p>14 A. And that's what FDA wanted out there. They</p> <p>15 didn't want it to rely on Prolift. They wanted it</p> <p>16 to be separate, that there was no literature for</p> <p>17 Prolift+M.</p> <p>18 Q. All right.</p> <p>19 A. And that was -- and then we went to the</p> <p>20 negotiation back and forth between -- and there's</p> <p>21 nothing wrong with negotiation. Manufacturers do it</p> <p>22 all the time.</p> <p>23 But in terms of adequate conveying to a</p> <p>24 surgeon, it watered it down so that the information</p> <p>25 would be lost.</p>
<p style="text-align: right;">Page 123</p> <p>1 the message, which is there is no randomized</p> <p>2 clinical controlled trials.</p> <p>3 BY MR. GAGE:</p> <p>4 Q. I'm talking about the third sentence.</p> <p>5 A. Yeah, the information part.</p> <p>6 Q. "Information on the clinical performance of</p> <p>7 mesh for pelvic floor repairs is available in the</p> <p>8 published literature," now, you and I agree that</p> <p>9 sentence doesn't specifically relate to Prolift+M?</p> <p>10 A. Well, it's a garbage statement. I mean,</p> <p>11 it's a garbage statement --</p> <p>12 Q. That was where I was headed is is --</p> <p>13 A. It's a throw-out statement that you would</p> <p>14 give to a surgeon. Well, there's published</p> <p>15 literature on mesh. You don't think any surgeon</p> <p>16 already knows that.</p> <p>17 And so it really just -- it distracts from</p> <p>18 what the FDA's message was, that, yeah, there's mesh</p> <p>19 literature. Contact your sales rep. So it's</p> <p>20 basically taking away the thrust of the warning that</p> <p>21 the surgeon would have had that, beware, there's no</p> <p>22 information about this product.</p> <p>23 Q. In your opinion, should a surgeon implanting</p> <p>24 a Prolift+M consult the medical literature</p> <p>25 concerning mesh for pelvic floor repair before</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. Do you know why FDA or does FDA share your</p> <p>2 opinion that it was watered down and it was a trash</p> <p>3 statement -- or, excuse me.</p> <p>4 Was it FDA's opinion that this was garbage</p> <p>5 information and was a throwaway statement?</p> <p>6 A. Actually, if you read in my report, it was</p> <p>7 at the very end, that they were under a time</p> <p>8 constraint to get their MDUFA date. And so they</p> <p>9 negotiated. And from an FDA's point of view, it's</p> <p>10 better to get that in than not have anything at all.</p> <p>11 So from a public health, they're trying to</p> <p>12 negotiate what they could do in a MDUFA time frame,</p> <p>13 and they wanted to get this done. And so they</p> <p>14 accepted it. Nobody argues that they accepted it,</p> <p>15 but it was a much more robust request by the FDA</p> <p>16 just to have that one line all by itself.</p> <p>17 Q. All right. Let's go down to adverse</p> <p>18 reactions.</p> <p>19 Do you see those?</p> <p>20 A. Yes, sir.</p> <p>21 Q. Do you recall having read the adverse</p> <p>22 reactions section of this Prolift+M IFU before</p> <p>23 today?</p> <p>24 A. Yes, sir.</p> <p>25 Q. Where did you read it?</p>

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<p style="text-align: right;">Page 126</p> <p>1 A. In terms of the 510(k), there was 2 information about the Prolift+M, and then the 3 discussion back and forth with the FDA as to those 4 sections. So it was primarily in the 510(k). 5 Q. It says, "Potential" -- the first bullet 6 says, "Potential adverse reactions are those 7 typically associated with surgery employing 8 implantable materials of this type, including 9 hematoma, urinary incontinence, ureter -- urinary 10 retention/obstruction, ureter obstruction, voiding 11 dysfunction, pain, infection potentiation, wound 12 dehiscence, nerve damage, or current prolapse, 13 inflammation, adhesion formation, fistula formation, 14 contracture or scarring, and mesh exposure, erosion, 15 or extrusion." 16 Did I read that correctly? 17 A. Yes, you did. 18 Q. What do those words communicate to a pelvic 19 floor surgeon? 20 A. Nothing specific about Prolift+M. They 21 would look at that and they would go, those are all 22 the things that typically can occur after urinary 23 surgery. 24 But it's not specifically -- it's not robust 25 when it doesn't say, "This has been reported for</p>	<p style="text-align: right;">Page 128</p> <p>1 didn't have that information. But then for a 2 510(k), they can immediately update their 3 information with the -- with the postmarket 4 performance of this product. 5 Q. Should a pelvic floor surgeon implant a mesh 6 device if they don't have any frequency data with 7 regard to adverse events specific to that device? 8 MR. JONES: Objection. 9 THE WITNESS: Well, that's what the -- 10 that's what the line up there about, "There's no 11 safety and efficacy information about this product." 12 I mean, that should give a surgeon a little bit of 13 pause if they really realize that there was no 14 information about these risks. 15 You know, in terms of that, that 16 would -- in terms of some other product, it should 17 make a physician think about it. 18 BY MR. GAGE: 19 Q. So a surgeon reading this IFU would know 20 it's not -- the Prolift+M has not been tested; 21 correct? 22 MR. AYLSTOCK: Objection to form. 23 THE WITNESS: No, not the way they go 24 on about the mesh stuff and then right underneath 25 they're going to be talking about Prolift.</p>
<p style="text-align: right;">Page 127</p> <p>1 this product." You know, "We have risks of this." 2 And we think of this, particularly as this 3 product was on the market, that it should have been 4 updated with, what is the report of urinary 5 retention with Prolift+M? How frequent is it 6 occurring? 7 So you're going to have a list of things 8 here, but it's not going to mean anything to the 9 doctor because he's going to go, "Oh, yeah. I know 10 these things can happen when you use mesh." 11 Q. If the frequency -- I take it your one -- 12 your criticism there is there's no product-specific 13 frequency in the adverse reactions section; correct? 14 MR. JONES: Objection. 15 THE WITNESS: That would be, and it 16 would be something -- when this first came out -- 17 BY MR. GAGE: 18 Q. Could you just answer -- would you answer 19 that? 20 A. Yes. 21 Q. And if you could answer it "yes," and then 22 give your explanation, I think that would be 23 helpful. 24 A. Well, yes. But the thing is -- I will give 25 them, when they first went on the market, they</p>	<p style="text-align: right;">Page 129</p> <p>1 BY MR. GAGE: 2 Q. I'm sorry. 3 A surgeon reading this Prolift+M IFU would 4 know that there have been no randomized clinical 5 trials involving Prolift+M? 6 A. That's what they have up in that first line 7 and then if you look underneath -- 8 Q. Hang on. Let me -- 9 MR. AYLSTOCK: Let her finish. 10 THE WITNESS: If you look underneath, 11 they go on and start talking about clinical 12 performance for Prolift. 13 Now, remember, FDA had asked that the 14 company not put Prolift in this because they look at 15 these as two different products. But the company 16 went ahead and put Prolift in here, which implies 17 that somehow Prolift is going to somehow give the 18 information for Prolift+M. 19 MR. GAGE: I move to strike everything 20 after the initial response to the question. 21 BY MR. GAGE: 22 Q. Would a surgeon reading the Prolift+M IFU 23 know from reading this IFU that Prolift+M had not 24 been studied in randomized clinical trials? Yes or 25 no? If you can answer that yes or no.</p>

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<p style="text-align: right;">Page 130</p> <p>1 A. Well, we have that statement up there --</p> <p>2 Q. Can you answer that --</p> <p>3 A. -- so yes.</p> <p>4 Q. -- can you answer that yes or no?</p> <p>5 MR. JONES: Objection.</p> <p>6 THE WITNESS: Well, I can't speak for</p> <p>7 what any one surgeon would know, but I can speak as</p> <p>8 a regulatory expert.</p> <p>9 BY MR. GAGE:</p> <p>10 Q. Dr. Parisian --</p> <p>11 MR. JONES: Let her finish.</p> <p>12 THE WITNESS: There's only one</p> <p>13 statement there, so they would know from that one</p> <p>14 statement that it's not been in randomized</p> <p>15 controlled studies, yes.</p> <p>16 BY MR. GAGE:</p> <p>17 Q. Thank you.</p> <p>18 A. But then they go on to talk about the</p> <p>19 clinical performance, and it implies that Prolift is</p> <p>20 translatable to Prolift+M, which we know it's not,</p> <p>21 and so it's misleading.</p> <p>22 We have one statement up above where it says</p> <p>23 there's no randomized control. Then we have mesh</p> <p>24 literature being referenced. So any one physician,</p> <p>25 I can't speak for what they would know, but I can</p>	<p style="text-align: right;">Page 132</p> <p>1 they're not usually studied that way. So it really</p> <p>2 is kind of like a statement, like, what does it mean</p> <p>3 when you go on and then you talk about the mesh</p> <p>4 literature, you're talking about the clinical</p> <p>5 performance below, so it's confusing.</p> <p>6 Yes, but surgical devices are not usually</p> <p>7 studied in randomized well-controlled studies.</p> <p>8 MR. GAGE: All right. Move to strike</p> <p>9 everything after the word "but."</p> <p>10 That -- that was -- thank you. I</p> <p>11 finally now understand.</p> <p>12 BY MR. GAGE:</p> <p>13 Q. All right. Now, Dr. Parisian, with regard</p> <p>14 to the adverse reactions, would a surgeon understand</p> <p>15 from reading this Prolift+M IFU that he or she, if</p> <p>16 they chose to implant a Prolift+M, if all they</p> <p>17 consulted was the Prolift+M IFU, they would be</p> <p>18 implanting a device without knowledge of the</p> <p>19 frequency of the adverse events that are listed in</p> <p>20 the adverse reactions section?</p> <p>21 A. Can you say that again?</p> <p>22 Q. Yeah.</p> <p>23 Would a -- would a surgeon reading this</p> <p>24 Prolift+M IFU have any information about the</p> <p>25 frequency of adverse events from reading this</p>
<p style="text-align: right;">Page 131</p> <p>1 say, from the way it's designed as a regulatory</p> <p>2 expert or an FDA and a physician, it's misleading.</p> <p>3 It's -- it's vague. It's like you don't understand</p> <p>4 what's going on here.</p> <p>5 Q. So you don't believe -- I just want to make</p> <p>6 sure I understand, because I'm struggling to</p> <p>7 understand you -- that a surgeon who reads the</p> <p>8 sentence, quote, The safety and effectiveness of the</p> <p>9 Gynecare Prolift+M system compared to conventional</p> <p>10 surgical repair for pelvic organ prolapse have not</p> <p>11 been demonstrated in randomized controlled clinical</p> <p>12 trials, period, closed quote --</p> <p>13 MR. JONES: Objection.</p> <p>14 BY MR. GAGE:</p> <p>15 Q. -- that a surgeon reading that sentence</p> <p>16 would -- would, because of additional sentences,</p> <p>17 believe that the device had been studied in</p> <p>18 randomized controlled clinical trials?</p> <p>19 MR. JONES: Objection.</p> <p>20 THE WITNESS: You see in -- no. A</p> <p>21 surgeon would believe that there was no randomized</p> <p>22 well-controlled study, yes.</p> <p>23 BY MR. GAGE:</p> <p>24 Q. That was my question.</p> <p>25 A. But this is a medical device in surgery, and</p>	<p style="text-align: right;">Page 133</p> <p>1 Prolift+M IFU?</p> <p>2 A. No.</p> <p>3 Q. So if a surgeon chose to implant a Prolift+M</p> <p>4 IFU, they would have to go elsewhere for information</p> <p>5 about the frequency of those adverse events;</p> <p>6 correct?</p> <p>7 MR. JONES: Objection.</p> <p>8 THE WITNESS: No. They're supposed to</p> <p>9 have it in the label. An adequate label should have</p> <p>10 it.</p> <p>11 MR. GAGE: Move to strike. It's not</p> <p>12 responsive.</p> <p>13 Could you repeat the question?</p> <p>14 (Requested portion was read by the</p> <p>15 Court Reporter.)</p> <p>16 MR. JONES: Same objection.</p> <p>17 THE WITNESS: No. Because if you -- if</p> <p>18 you look -- if, one, they required an adequate</p> <p>19 label, and, No. 2, if you look at the potential</p> <p>20 adverse reactions, nothing is there about chronic.</p> <p>21 I mean, surgeons would think that a lot</p> <p>22 of this stuff are acute, but there's nothing about</p> <p>23 these being chronic.</p> <p>24 MR. GAGE: Excuse me, Dr. Parisian. I</p> <p>25 have to move to strike the answer as nonresponsive.</p>

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<p style="text-align: right;">Page 134</p> <p>1 Could you read the question back?</p> <p>2 And I'm going to say, if the witness</p> <p>3 persists, I'm going to have to ask for more time.</p> <p>4 MR. JONES: She's answering the</p> <p>5 question.</p> <p>6 MR. GAGE: No, she's not. Not even</p> <p>7 close.</p> <p>8 MR. AYLSTOCK: She's absolutely</p> <p>9 answering the question.</p> <p>10 MR. GAGE: Not even close.</p> <p>11 So could you read the question back one</p> <p>12 more time?</p> <p>13 (Requested portion was read by the</p> <p>14 Court Reporter.)</p> <p>15 MR. JONES: Objection.</p> <p>16 THE WITNESS: Yes, they would, because</p> <p>17 they're certainly not in the label. It's not an</p> <p>18 adequate label.</p> <p>19 MR. GAGE: Move to strike everything</p> <p>20 after the word "yes."</p> <p>21 BY MR. GAGE:</p> <p>22 Q. And is it your opinion that the adverse</p> <p>23 reactions that are listed in the Prolift+M IFU do</p> <p>24 not communicate that those are potential risks of</p> <p>25 the Prolift+M?</p>	<p style="text-align: right;">Page 136</p> <p>1 adequate?</p> <p>2 A. You know, I haven't -- yeah, there's lots of</p> <p>3 devices that I have not been involved in. I mean,</p> <p>4 there's adequate labels.</p> <p>5 Are you saying that every device in the</p> <p>6 company -- country? I don't know.</p> <p>7 Q. Dr. Parisian, I'm asking you a question.</p> <p>8 Can you identify -- well, read the question</p> <p>9 back.</p> <p>10 (Requested portion was read by the</p> <p>11 Court Reporter.)</p> <p>12 THE WITNESS: I'm sure there's lots. I</p> <p>13 haven't developed that.</p> <p>14 BY MR. GAGE:</p> <p>15 Q. Okay. After Prolift+M was cleared, did FDA</p> <p>16 ever recommend any labeling changes for Prolift+M</p> <p>17 IFU or patient brochure?</p> <p>18 A. I don't recall that they did.</p> <p>19 Q. Has FDA ever determined that the Prolift+M</p> <p>20 IFU or patient brochure were false or misleading?</p> <p>21 A. Not that I'm aware of in terms of writing,</p> <p>22 and you're talking about a letter or something. I</p> <p>23 haven't seen a letter to that effect.</p> <p>24 Q. Has FDA ever declared the Prolift+M IFU or</p> <p>25 patient brochure to be inadequate after the device</p>
<p style="text-align: right;">Page 135</p> <p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 A. And that they can be chronic, not just</p> <p>4 acute, because that list is primarily acute</p> <p>5 complications post-surgery.</p> <p>6 MR. GAGE: Move to strike everything</p> <p>7 after the word "yes" as nonresponsive.</p> <p>8 BY MR. GAGE:</p> <p>9 Q. Dr. Parisian, do you -- you've looked at a</p> <p>10 number of mesh IFUs in connection with your expert</p> <p>11 work. Is that correct?</p> <p>12 A. Yes, sir.</p> <p>13 Q. Have you found one that's adequate?</p> <p>14 A. Not in the cases I've been involved. I</p> <p>15 haven't looked at every single one. I haven't</p> <p>16 looked at every single one. I'm not involved in</p> <p>17 every single case, so . . .</p> <p>18 Q. Of the IFUs that you have looked at, have</p> <p>19 you found any that are adequate?</p> <p>20 A. No. Not -- not the cases I've taken, no.</p> <p>21 Q. Have you found any that have frequency data</p> <p>22 with regard to adverse events?</p> <p>23 A. I don't recall.</p> <p>24 Q. Can you point me to any medical device IFU</p> <p>25 for any type of a medical device that you believe is</p>	<p style="text-align: right;">Page 137</p> <p>1 was cleared?</p> <p>2 A. After it was cleared, no. I haven't seen</p> <p>3 anything from the FDA.</p> <p>4 Q. And FDA has never determined the Prolift+M</p> <p>5 device was misbranded or adulterated; correct?</p> <p>6 A. Correct. There's no official ruling like</p> <p>7 that, yes, sir.</p> <p>8 Q. Does FDA have the power to make a device</p> <p>9 manufacturer change the wording in its IFU or</p> <p>10 patient brochure?</p> <p>11 MR. JONES: Objection.</p> <p>12 THE WITNESS: The power? They have the</p> <p>13 authority. Do they ever use it? No. They try to</p> <p>14 get voluntary compliance.</p> <p>15 BY MR. GAGE:</p> <p>16 Q. Has Ethicon -- I'm sorry. Strike that.</p> <p>17 Has FDA ever concluded that Ethicon failed</p> <p>18 to provide safety information to FDA that was</p> <p>19 pertinent to Prolift+M?</p> <p>20 A. Well, the Prolift. That was a 510(k),</p> <p>21 remember, that they were asking for the Prolift --</p> <p>22 they hadn't given them the clinical trials, so</p> <p>23 there's some interaction there. They didn't do a</p> <p>24 ruling or some kind of a document, but they did make</p> <p>25 them give them the information for it.</p>

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<p style="text-align: right;">Page 138</p> <p>1 Q. I think my question, though, was specific to</p> <p>2 Prolift+M.</p> <p>3 A. Right.</p> <p>4 But Prolift fed into Prolift+M in terms of</p> <p>5 the 510(k), because they said that it wasn't the</p> <p>6 predicate. They made them give the French</p> <p>7 information, the other studies.</p> <p>8 Q. Let me ask the question a different way.</p> <p>9 A. Okay.</p> <p>10 Q. After May of 2008, did FDA ever conclude</p> <p>11 that Ethicon failed to provide safety information to</p> <p>12 FDA that was pertinent to Prolift+M?</p> <p>13 A. Not that I've seen.</p> <p>14 Q. Did FDA ever request or order that Prolift+M</p> <p>15 be withdrawn from the market?</p> <p>16 A. No.</p> <p>17 Q. Did FDA ever declare the Prolift+M was</p> <p>18 illegally marketed?</p> <p>19 A. No.</p> <p>20 Q. And we can agree FDA never recalled</p> <p>21 Prolift+M?</p> <p>22 A. Well, the FDA very rarely recalls anything,</p> <p>23 but it was never recalled by Johnson & Johnson.</p> <p>24 Q. Was Prolift+M ever recalled by the FDA?</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 140</p> <p>1 marketed.</p> <p>2 Q. Could -- could Ethicon have continued to</p> <p>3 market the Prolift+M while conducting the 522</p> <p>4 studies?</p> <p>5 A. They could have. They would have been</p> <p>6 required to. If they continued to market it, they</p> <p>7 would have had to do the 522 studies.</p> <p>8 Pulling it off allowed them to put it on</p> <p>9 hold basically, and -- and FDA had enough on their</p> <p>10 plate with the other studies, they didn't force them</p> <p>11 to do a postmarket study on the Prolift+M.</p> <p>12 Q. So FDA could have permitted Ethicon to</p> <p>13 continue marketing Prolift+M while the 522 studies</p> <p>14 were being conducted on Prolift+M; correct?</p> <p>15 A. Yeah, sure. That's not saying the FDA</p> <p>16 wanted them to, but it is a 510(k) cleared device.</p> <p>17 Q. Have you looked at any of the studies that</p> <p>18 other manufacturers have done in response to the 522</p> <p>19 orders?</p> <p>20 A. I've been looking at them, yeah. What do</p> <p>21 you want to know?</p> <p>22 Q. Well, I mean, have some of the manufactures</p> <p>23 completed those studies?</p> <p>24 A. I don't think they've completed them, and</p> <p>25 some of them are working with the physician groups</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. Did FDA ever determine that Prolift+M was</p> <p>2 not safe and effective?</p> <p>3 MR. JONES: Objection.</p> <p>4 THE WITNESS: Well, it was cleared.</p> <p>5 That was the only interaction with the FDA. FDA</p> <p>6 cleared it. So there's no debate that the FDA</p> <p>7 cleared it.</p> <p>8 BY MR. GAGE:</p> <p>9 Q. Now, Dr. Parisian, you indicated -- you</p> <p>10 mentioned in your report you had some information</p> <p>11 about the 522 studies.</p> <p>12 Do you remember that?</p> <p>13 A. Yes, sir.</p> <p>14 Q. Had Ethicon chosen to conduct the studies</p> <p>15 that FDA requested with regard to Prolift+M, is it</p> <p>16 correct that the Prolift+M device would have</p> <p>17 remained on the market while those studies were</p> <p>18 underway?</p> <p>19 A. You know, in terms of the 522, I don't think</p> <p>20 that's specified. You could have done a postmarket</p> <p>21 study for women who were implanted. You didn't need</p> <p>22 to keep marketing the Prolift+M.</p> <p>23 The company chose to pull it off the market</p> <p>24 and asked FDA to put it on hold. But if you look at</p> <p>25 the 522 process, it doesn't have to be commercially</p>	<p style="text-align: right;">Page 141</p> <p>1 to try to get information, postmarket information.</p> <p>2 I mean, in terms of the POP, they're going</p> <p>3 to have to come out with a PMA, so all the</p> <p>4 manufacturers of a POP device are going to have to</p> <p>5 come out --</p> <p>6 Q. What -- what devices have you seen 522</p> <p>7 studies or 522 interim results for thus far?</p> <p>8 A. I don't recall which ones that I've seen</p> <p>9 offhand. I think -- I thought Boston Scientific I</p> <p>10 saw some, but I don't remember. I haven't looked at</p> <p>11 them.</p> <p>12 Q. Have you spoken with any patients who have</p> <p>13 had a Prolift or a Prolift+M implanted in them?</p> <p>14 A. No.</p> <p>15 Q. And I assume you have not conducted any</p> <p>16 study or survey of women to determine what risks</p> <p>17 they may have been aware of as a result of reading</p> <p>18 the Prolift+M patient brochure?</p> <p>19 A. That's correct. I haven't done a study like</p> <p>20 that.</p> <p>21 Q. Do you know how many mesh manufacturers have</p> <p>22 patient brochures?</p> <p>23 A. No, I don't know how many.</p> <p>24 Q. Do you know if any of the manufacturers --</p> <p>25 well, let me ask you this: You're working in cases</p>

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<p style="text-align: right;">Page 142</p> <p>1 against Boston Scientific and Bard and AMS; correct?</p> <p>2 A. Not Bard.</p> <p>3 Q. Boston Scientific and AMS?</p> <p>4 A. AMS.</p> <p>5 Q. And Ethicon?</p> <p>6 A. And Ethicon.</p> <p>7 Q. Did Boston Scientific or AMS have patient</p> <p>8 brochures for their pelvic organ prolapse devices?</p> <p>9 A. I believe so.</p> <p>10 And then all around 2008, their patient</p> <p>11 brochures were changing because FDA was trying to</p> <p>12 get information -- negotiate information into the</p> <p>13 labels.</p> <p>14 So they've all had brochures, but 2008 seems</p> <p>15 to be when FDA was pushing to try to update it with</p> <p>16 what at least was in the medical literature.</p> <p>17 Q. Did you compare the Ethicon patient brochure</p> <p>18 for Prolift+M to any other manufacturer's pelvic</p> <p>19 organ prolapse patient brochure?</p> <p>20 A. No.</p> <p>21 Q. Do you know if the FDA ever commented on the</p> <p>22 adequacy or the inadequacy of the Prolift+M patient</p> <p>23 brochure?</p> <p>24 A. No, I don't remember seeing them comment on</p> <p>25 it.</p>	<p style="text-align: right;">Page 144</p> <p>1 The pre-amendment device classified Class 2 in 1988.</p> <p>2 No. It's just a fact.</p> <p>3 Q. Dr. Parisian, you indicated in your report</p> <p>4 that --</p> <p>5 A. Where are you?</p> <p>6 Q. Well, I'll read it to you.</p> <p>7 It says -- it's Paragraph 41. You say,</p> <p>8 "When Ethicon submitted the original Prolift+M</p> <p>9 510(k), FDA's ODE reviewers became aware that</p> <p>10 Prolift had marketed, quote, off label, closed</p> <p>11 quote, for years by Ethicon for POP without 510(k)</p> <p>12 clearance or an FDA-approved IDE. Yet, the</p> <p>13 premarket ODE branch pursued no official regulatory</p> <p>14 action or civil penalties against Ethicon for its</p> <p>15 violation of the act. ODE permitted Ethicon to add</p> <p>16 Prolift to its Prolift+M 510(k) submission. This</p> <p>17 was done at the regulatory discretion of the ODE</p> <p>18 review branch, and in the past, is a decision based</p> <p>19 on FDA resources and cost to the public."</p> <p>20 Do you see that?</p> <p>21 A. Um-hmm.</p> <p>22 Q. When you say "this was done" -- "this was</p> <p>23 done at the regulatory discretion of the ODE review</p> <p>24 branch, and is, in the past, a decision based on</p> <p>25 FDA's resources and cost to the public," does the</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. Dr. Parisian, I'll represent to you, with</p> <p>2 regard to Prolift -- and I'm not -- and I'm meaning</p> <p>3 specifically the Prolift, not Prolift+M. Okay?</p> <p>4 I'll represent to you that there are in</p> <p>5 excess of 3- to 400 studies of different types on</p> <p>6 the Prolift device.</p> <p>7 Does that surprise you?</p> <p>8 MR. JONES: Objection.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MR. GAGE:</p> <p>11 Q. On your reliance list, I saw that you had</p> <p>12 approximately 15 of those studies.</p> <p>13 Have you -- does that sound about right to</p> <p>14 you?</p> <p>15 A. Probably.</p> <p>16 Q. Have you endeavored to look at the other</p> <p>17 studies that are out there on Prolift?</p> <p>18 MR. JONES: Objection.</p> <p>19 THE WITNESS: No.</p> <p>20 BY MR. GAGE:</p> <p>21 Q. All right. Dr. Parisian, continuing, do you</p> <p>22 have any opinions about the process that led to the</p> <p>23 classification of surgical mesh in 1988?</p> <p>24 A. Do I have an opinion? No. I mean, it's</p> <p>25 just a fact it was a pre-amendment classification.</p>	<p style="text-align: right;">Page 145</p> <p>1 word "this" mean FDA allowing Ethicon to add Prolift</p> <p>2 to the Prolift+M 510(k)?</p> <p>3 A. Yes, sir.</p> <p>4 Q. Okay. In the preceding sentence, you say,</p> <p>5 "The premarket ODE branch pursued no official</p> <p>6 regulatory action or civil penalties against Ethicon</p> <p>7 for its violation of the act," do you know why they</p> <p>8 chose to not do that?</p> <p>9 A. It takes a lot of time and effort and</p> <p>10 resources, like I said. It's just their choice.</p> <p>11 You could have -- you could have not done</p> <p>12 that. That was what their choice was. Do I know</p> <p>13 why? No. That's how they chose to handle it.</p> <p>14 Q. Does FDA's perception of the company's</p> <p>15 acting in good faith or lack of acting in good faith</p> <p>16 factor into that discretion?</p> <p>17 A. No. A lot of it has to do with the effort</p> <p>18 that it would take to bring some kind of a</p> <p>19 regulatory action. This way, we can just -- in</p> <p>20 terms of the process, they can just clear the</p> <p>21 510(k).</p> <p>22 Q. Okay. So could -- I'm going to ask the</p> <p>23 question again. I'm going to ask the court reporter</p> <p>24 to ask that question again because I'm not sure</p> <p>25 you -- if you will listen very specifically to the</p>

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<p style="text-align: right;">Page 146</p> <p>1 wording of it. I want to make sure that you heard</p> <p>2 it and you are answering that particular question.</p> <p>3 (Requested portion was read by the</p> <p>4 Court Reporter.)</p> <p>5 THE WITNESS: Not necessarily from my</p> <p>6 experience. Usually it is, what is the company -- I</p> <p>7 can't make what the intent of the FDA was. It's a</p> <p>8 fact that they did that.</p> <p>9 Have I seen situations in the past when</p> <p>10 I was there and they did that? Yes, but it's not</p> <p>11 necessarily what the company's -- what the FDA is</p> <p>12 thinking about the company.</p> <p>13 It's basically, what would be the</p> <p>14 effort that it would take to bring a regulatory</p> <p>15 action against the company, what does it solve, and</p> <p>16 so they just chose this path.</p> <p>17 BY MR. GAGE:</p> <p>18 Q. Have you seen any statements from FDA about</p> <p>19 whether FDA believed Ethicon was acting in good</p> <p>20 faith with regard to this issue?</p> <p>21 A. Not at the time. That's why I looked at</p> <p>22 that document that we have from 2007, 2008, when the</p> <p>23 FDA was talking about -- they were specifically</p> <p>24 focusing on Ethicon.</p> <p>25 Q. And just to be clear, you're talking about</p>	<p style="text-align: right;">Page 148</p> <p>1 they've been changed. They've been altered. And if</p> <p>2 you were at FDA, you would hardly ever read those</p> <p>3 things to see that they've been altered, but these</p> <p>4 were.</p> <p>5 Q. On page 71 of your report in Paragraph 197,</p> <p>6 you have a sentence that says, "Without any</p> <p>7 explanation, or perhaps as an error in typing,</p> <p>8 Ethicon changed the statement in the original 510(k)</p> <p>9 submitted June 2007 and repeated the same error in</p> <p>10 wording and certification in its submission of</p> <p>11 September 19, 2007, significantly narrowing the</p> <p>12 truthful and accuracy scope only to the SE</p> <p>13 decision."</p> <p>14 A. Yes.</p> <p>15 Q. Do you recall that?</p> <p>16 A. Yes. And I stated there that I don't know</p> <p>17 why it occurred, so I don't know why it occurred.</p> <p>18 But whatever it is, it seems to be occurring in</p> <p>19 their 510(k)s, and it did narrow the scope to that</p> <p>20 no material fact for the substantial equivalence</p> <p>21 decision had not been provided.</p> <p>22 Q. Have any of the documents that you have</p> <p>23 reviewed since you wrote this report or any of the</p> <p>24 information you may have received to gather,</p> <p>25 investigate, or research since you wrote this report</p>
<p style="text-align: right;">Page 147</p> <p>1 the -- Exhibit 6?</p> <p>2 A. Right.</p> <p>3 Q. Okay.</p> <p>4 A. And so at that time, I don't see where</p> <p>5 they're talking anything about good faith. They're</p> <p>6 talking about that the product had been marketed,</p> <p>7 and FDA was trying to figure out how to catch up</p> <p>8 with this issue.</p> <p>9 So there may be some statement somewhere,</p> <p>10 but from the documents that I saw, there wasn't</p> <p>11 anything in this period of time.</p> <p>12 Q. Okay. So if there is such a statement, you</p> <p>13 haven't seen it?</p> <p>14 A. I haven't seen it, and I would have to look</p> <p>15 at it and put it in context with what was going on.</p> <p>16 But also having been there, I know that ODE is not</p> <p>17 one to usually trigger a compliance action, which</p> <p>18 would have been Office of Compliance postmarket.</p> <p>19 Q. In your report in several places, you</p> <p>20 discuss that certain certifications signed by</p> <p>21 Ethicon were not in compliance with regulations</p> <p>22 according to you.</p> <p>23 Do you recall those statements?</p> <p>24 A. I didn't say noncompliance, but they're not</p> <p>25 consistent with what the normal statement is, and</p>	<p style="text-align: right;">Page 149</p> <p>1 given you any additional information that would</p> <p>2 allow you to say one way or the other as to whether</p> <p>3 that was an error in typing or whether it was</p> <p>4 something other than an error in typing?</p> <p>5 A. No.</p> <p>6 Q. In Paragraph 231 on page 83 of your report,</p> <p>7 you say, "Thus, PFR and use of laser cutting of PE</p> <p>8 mesh into new complex shapes introduced new and</p> <p>9 unaddressed issues of safety and effectiveness for</p> <p>10 PFR not seen with TVT, SUI, or the AMS predicates.</p> <p>11 These new issues were not studied by Ethicon."</p> <p>12 Do you remember that?</p> <p>13 A. Yes, sir.</p> <p>14 Q. Have you seen any clinical data that</p> <p>15 indicates that laser cut mesh is dangerous to</p> <p>16 patients?</p> <p>17 A. No. It's just -- in terms of the laser cut</p> <p>18 mesh, it changes the edge in terms of the -- the</p> <p>19 potential for rubbing. It's just -- it's not like</p> <p>20 you're going to see laser cut is dangerous. It's</p> <p>21 something you need to consider in terms of the</p> <p>22 forces and the change in the plastic mesh.</p> <p>23 I mean, it's just a visual difference</p> <p>24 between machine cut and laser cut mesh.</p> <p>25 Q. But you have not seen any clinical data</p>

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<p style="text-align: right;">Page 150</p> <p>1 comparing laser cut to machine cut mesh in terms of 2 patient outcomes, have you? 3 A. I haven't looked for that in terms of POP. 4 It is a difference between TVT, TVT-O, and TVT-S, 5 and also in terms of the difference for a Prolift. 6 So it's something to be considered in terms of 7 design. 8 Q. Dr. Parisian, you're generally aware that 9 the -- and I believe you've mentioned in your report 10 in various places that plaintiffs allege, and I 11 believe you have opinions that address certain 12 alleged defects in the mesh itself, such as the 13 propensity of the mesh to cause excessive 14 inflammation. Is that -- I mean, that's one of your 15 opinions; correct? 16 A. Where are you getting that opinion from, I 17 mean, because I know that there's going to be other 18 people talking about the mesh properties? 19 But in terms of the inflammatory response 20 that you have in patients, are you looking at a 21 specific thing in my report? 22 Q. I think in your TVT-Secur report, you 23 indicated issues like pore size, weight -- pore size 24 and weight of the mesh as being issues for your 25 TVT-Secur?</p>	<p style="text-align: right;">Page 152</p> <p>1 A. They're not put in intra-vaginally. 2 Q. Correct. 3 A. So, yes, you can use it intra-abdominally. 4 Q. And that's acceptable with FDA; correct? 5 A. Right now it is because the FDA has only 6 made the 522s occur for the transvaginal mesh. 7 Q. Right. 8 There are no 522 orders for the abdominal 9 meshes; correct? 10 A. Not that I'm aware of. 11 Q. Do you know if GYNEMESH PS is made of the 12 same material that is found in Prolift+M? 13 MR. JONES: Objection. 14 THE WITNESS: Well, the Prolift is 15 GYNEMESH PS. Prolift+M is -- is different. It's 16 ULTRAPRO. And so it's -- it's kind of -- with the 17 Monocryl that's woven into the underlying mesh. 18 Neither one of them are PROLENE. PROLENE is the 19 TVT-S, the T- -- the TVT family is PROLENE. 20 BY MR. GAGE: 21 Q. Is Prolift+M made of PROLENE? 22 A. It's ULTRAPRO, which is -- I mean, they're 23 all polypropylene, but it's a different weave and a 24 different mesh than polypropylene, because 25 supposedly when the Monocryl is gone, you have a</p>
<p style="text-align: right;">Page 151</p> <p>1 A. I mean, you're talking about that one table, 2 I think, on page 48? 3 Q. I don't have the specific -- I've got it -- 4 A. Those -- those are the evolution -- I think 5 where -- and if that's one table that you're 6 thinking of, I think that's just the evolution of 7 mesh is basically -- because TVT is just your basic 8 old PROLENE mesh, which is a heavy mesh with a -- 9 Q. I'll tell you what. Let me -- let me 10 move -- because my time is limited, I want to keep 11 moving here, so let me ask it in a different way. 12 Is PROLENE mesh -- can PROLENE mesh be used 13 in the United States for pelvic organ prolapse 14 repair? 15 A. Well, it is right now, TVT, TVT-O. 16 Q. Well, that's stress urinary incontinence. 17 I'm talking about the pelvic organ prolapse. 18 A. Oh, pelvic organ prolapse? Right now I 19 don't think the company is selling it. Is it? I 20 mean, they don't have a product with PROLENE mesh. 21 Q. You're familiar with GYNEMESH PS? 22 A. Right. 23 Q. And ARTISYN? 24 A. Right. And those are put in abdominally. 25 Q. Correct.</p>	<p style="text-align: right;">Page 153</p> <p>1 lighter weight mesh. You have also more of the 2 bigger pores when the Monocryl's gone. I think it's 3 like 20 to 30 grams per millimeter squared. 4 Q. Is the polypropylene in Prolift+M PROLENE, 5 or is it some other substance? 6 MR. JONES: Objection. 7 THE WITNESS: Well, they're all 8 polypropylene. They're all the same resin source, 9 which would be your Phillips, Chevron, whatever, 10 polypropylene. So it's -- it's all that same resin. 11 It's just you change your mesh in terms 12 of your weave. Like, if you take GYNEMESH PS, it's 13 a lighter mesh so -- but the very original mother of 14 all of this was PROLENE, which is your heavier mesh. 15 And I think it only has a porosity of 49 percent 16 porous compared to the mesh fabric. 17 BY MR. GAGE: 18 Q. Are there any differences in the chemical 19 makeup of the polypropylene and PROLENE in Prolift+M 20 as compared to Prolift or TVT? 21 MR. JONES: Objection. 22 THE WITNESS: Well, they're all 23 polypropylene. Is that what you're asking me? 24 BY MR. GAGE: 25 Q. Are they all the same type of polypropylene?</p>

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<p style="text-align: right;">Page 154</p> <p>1 MR. JONES: At what point?</p> <p>2 THE WITNESS: Well, they're not all --</p> <p>3 they're different weaves. They're different</p> <p>4 families.</p> <p>5 BY MR. GAGE:</p> <p>6 Q. I'm not talking about weave. I'm talking</p> <p>7 about the chemical makeup.</p> <p>8 Is the -- is the polypropylene in Prolift+M</p> <p>9 made of the same chemicals and substances that are</p> <p>10 found in the polypropylene in Prolift and TVT?</p> <p>11 MR. JONES: Objection.</p> <p>12 THE WITNESS: Right. It's the same</p> <p>13 resin, polypropylene resin.</p> <p>14 BY MR. GAGE:</p> <p>15 Q. All right. What do you make, if anything,</p> <p>16 of the fact that the FDA permits the use of PROLENE</p> <p>17 mesh for pelvic organ prolapse repair abdominally?</p> <p>18 A. Oh, I know -- I mean, in terms of -- it's a</p> <p>19 long, tortious history. Remember, surgical mesh</p> <p>20 began as a pre-amendment device.</p> <p>21 Q. I'll withdraw the question.</p> <p>22 Dr. Parisian, are you familiar with the</p> <p>23 phrase "valid scientific evidence"?</p> <p>24 A. Yeah.</p> <p>25 Q. Dr. Parisian, in order for a new mesh device</p>	<p style="text-align: right;">Page 156</p> <p>1 animals first before I go and jump into women.</p> <p>2 Q. All right. If animal studies are done, do</p> <p>3 you believe that women -- female studies should be</p> <p>4 done before it's marketed?</p> <p>5 A. Well, yes, to get robust information in</p> <p>6 terms of your valid evidence, that you would have a</p> <p>7 situation where you actually are monitoring the</p> <p>8 women and you can test, and you get the data from</p> <p>9 them, so it's more robust.</p> <p>10 The 510(k) process allowed them not to have</p> <p>11 that, but it would be more robust for a manufacturer</p> <p>12 to have that information.</p> <p>13 Q. Do you know how many women would need to be</p> <p>14 the subject of a clinical study using that new mesh</p> <p>15 design before it could be declared safe and</p> <p>16 effective?</p> <p>17 A. No. Because that would -- if you're talking</p> <p>18 about safe and effective, you're talking about a</p> <p>19 PMA, and I don't know what the FDA is going to say</p> <p>20 in terms of the PMA for these products.</p> <p>21 Q. Do you know how long such a study should</p> <p>22 last?</p> <p>23 A. No. I don't know how -- I don't know how</p> <p>24 long FDA is going to -- they usually will --</p> <p>25 Q. Well, putting aside the FDA, I'm talking</p>
<p style="text-align: right;">Page 155</p> <p>1 to be adequately tested for permanent implantation</p> <p>2 in women, does it need to be supported by valid</p> <p>3 scientific evidence?</p> <p>4 A. Did you say for POP?</p> <p>5 Q. I'll withdraw the question and re-ask it.</p> <p>6 Dr. Parisian, in order for a new mesh device</p> <p>7 for pelvic organ prolapse to be adequately tested</p> <p>8 for permanent implantation in women, does it need to</p> <p>9 be supported by valid scientific evidence?</p> <p>10 A. Not yet. It will when they have to do a PMA</p> <p>11 for a POP device.</p> <p>12 Q. Would it be reasonable for a manufacturer of</p> <p>13 a new pelvic organ prolapse mesh device to test it</p> <p>14 in women before it's marketed?</p> <p>15 A. It depends. It depends. Because the FDA is</p> <p>16 still going to probably allow them to -- since</p> <p>17 polypropylene is grandfathered in, they're going to</p> <p>18 allow them not to specifically look at that mesh,</p> <p>19 because that's the way the FDA is, and you can start</p> <p>20 with animal studies before you go to humans. And</p> <p>21 so --</p> <p>22 Q. Well, if you have a new polypropylene mesh</p> <p>23 device that you wanted to market, do you believe it</p> <p>24 should be tested in live women before it's marketed?</p> <p>25 A. It depends. I mean, I would start with</p>	<p style="text-align: right;">Page 157</p> <p>1 just you, Suzanne Parisian, Dr. Parisian --</p> <p>2 A. Okay.</p> <p>3 Q. -- with your experience and your talent, can</p> <p>4 you tell me how long such a study should be</p> <p>5 conducted in live women before a new mesh POP device</p> <p>6 is marketed?</p> <p>7 MR. JONES: Objection.</p> <p>8 THE WITNESS: Well, it's going to be a</p> <p>9 minimum of a year. I mean, you need to have a year</p> <p>10 at least, and then usually you're going to have at</p> <p>11 least five years data accumulated. The FDA may</p> <p>12 clear something before that.</p> <p>13 Remember, all these devices, FDA, when</p> <p>14 I've seen what they're trying to say, all these</p> <p>15 devices had long histories. So the FDA has been</p> <p>16 encouraging the people doing the 522s, if you're</p> <p>17 going to want a PMA, that you actually incorporate</p> <p>18 your current product that you're using in order to</p> <p>19 have longer term data, five-year data, when you come</p> <p>20 in with a PMA.</p> <p>21 BY MR. GAGE:</p> <p>22 Q. Dr. Parisian, did you endeavor to gather</p> <p>23 MAUDE reports on Prolift+M?</p> <p>24 A. No.</p> <p>25 Q. So is it fair to say that you are not going</p>

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<p style="text-align: right;">Page 158</p> <p>1 to render an opinion that specific issue reports or</p> <p>2 specific patient events regarding Prolift+M were not</p> <p>3 properly reported to FDA by Ethicon?</p> <p>4 A. I haven't looked for specific events. I</p> <p>5 think what was more would be the IFU. What was it</p> <p>6 the company knew internally and what should they</p> <p>7 have put in their IFU.</p> <p>8 Q. Have you undertaken a review or an analysis</p> <p>9 of the company's issue reports with regard to</p> <p>10 Prolift+M?</p> <p>11 A. I don't believe I have.</p> <p>12 Q. Okay.</p> <p>13 A. Because you're talking about like the</p> <p>14 complaint files and the CAPA?</p> <p>15 Q. Yes.</p> <p>16 A. I haven't looked at all that.</p> <p>17 Q. Dr. Parisian, you are -- well, let me ask</p> <p>18 you this: Dr. Parisian, have you seen any of the</p> <p>19 television advertisements with regards to pelvic</p> <p>20 mesh?</p> <p>21 A. I see something pop up on television.</p> <p>22 Nothing specific.</p> <p>23 Q. Have you examined that issue in connection</p> <p>24 with your work for any of the mesh litigation that</p> <p>25 you're involved in?</p>	<p style="text-align: right;">Page 160</p> <p>1 and it's a patient brochure.</p> <p>2 Q. Was this among the documents that you -- as</p> <p>3 I understand it -- strike that.</p> <p>4 As I understand it, there have been several</p> <p>5 versions of various patient brochures that you've</p> <p>6 reviewed; correct?</p> <p>7 A. Yes, sir.</p> <p>8 Q. Do you know which ones pertain specifically</p> <p>9 to Prolift versus -- Prolift+M as opposed to other</p> <p>10 of the Ethicon devices?</p> <p>11 A. No.</p> <p>12 I was trying to get what date this was.</p> <p>13 Q. So why don't you flip through this one?</p> <p>14 A. This one is in color. See, I haven't seen</p> <p>15 them in color.</p> <p>16 Q. Why don't you flip through this one?</p> <p>17 A. Okay.</p> <p>18 Q. And when you've had a chance to flip through</p> <p>19 it, just let me know.</p> <p>20 A. Okay.</p> <p>21 Q. Have you had a chance?</p> <p>22 A. Yes, sir.</p> <p>23 Q. Okay. Have you seen this specific patient</p> <p>24 brochure before?</p> <p>25 A. I don't know if I've seen this one. I've</p>
<p style="text-align: right;">Page 159</p> <p>1 A. No.</p> <p>2 Q. Does -- do -- does mesh advertising</p> <p>3 potentially bias a patient in favor of reporting or</p> <p>4 seeking legal counsel?</p> <p>5 A. I don't know.</p> <p>6 Q. Have you looked at any of those issues with</p> <p>7 regard to lawyer advertising?</p> <p>8 A. No.</p> <p>9 Q. Have you attempted to examine how many</p> <p>10 lawsuits have been filed regarding Prolift+M?</p> <p>11 A. No.</p> <p>12 Q. All right.</p> <p>13 MR. GAGE: Can we just go off the</p> <p>14 record for a second?</p> <p>15 (Recess taken.)</p> <p>16 (Whereupon, Exhibit No. 18 was marked</p> <p>17 for identification.)</p> <p>18 BY MR. GAGE:</p> <p>19 Q. Dr. Parisian, I'm going to hand you a</p> <p>20 document marked as Exhibit No. 18.</p> <p>21 A. Thank you.</p> <p>22 Q. Have you ever seen that document before?</p> <p>23 A. Yes.</p> <p>24 Q. What is that document?</p> <p>25 A. That is a Gynecare, and it's got Prolift+M,</p>	<p style="text-align: right;">Page 161</p> <p>1 seen something like this one. I don't know what the</p> <p>2 Prosima is.</p> <p>3 Q. Okay. So if this document does not appear</p> <p>4 on your reliance list, would it be fair to say that</p> <p>5 this is the first time you've seen this specific</p> <p>6 patient brochure?</p> <p>7 MR. JONES: Objection.</p> <p>8 MR. AYLSTOCK: Objection to form.</p> <p>9 THE WITNESS: This one, yes. In color,</p> <p>10 yes. I've seen a patient brochure but usually</p> <p>11 they're drafts are what I've seen from the 510(k).</p> <p>12 BY MR. GAGE:</p> <p>13 Q. All right. If we -- let me ask the same</p> <p>14 question, if we took the color out, have you seen</p> <p>15 this patient brochure in its -- in its black and</p> <p>16 white version?</p> <p>17 A. I may have because the pictures of the</p> <p>18 people look familiar.</p> <p>19 Q. If the -- if your reliance list does not</p> <p>20 contain this document, would it be fair to say that</p> <p>21 today is the first time you've seen this specific</p> <p>22 patient brochure?</p> <p>23 MR. JONES: Objection.</p> <p>24 MR. AYLSTOCK: Objection to form.</p> <p>25 THE WITNESS: If it's not in the</p>

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<p style="text-align: right;">Page 162</p> <p>1 510(k) -- because there is something in the 510(k)</p> <p>2 about their -- their patient brochure, I think, so</p> <p>3 I've seen something, but I don't know. This one may</p> <p>4 be the first time, yes.</p> <p>5 BY MR. GAGE:</p> <p>6 Q. All right. Dr. Parisian --</p> <p>7 A. No questions?</p> <p>8 Q. Oh, just a couple more. My last few minutes</p> <p>9 here. I want to go back to the concept of valid</p> <p>10 scientific evidence.</p> <p>11 Dr. Parisian, are well-controlled</p> <p>12 investigations considered to be valid scientific</p> <p>13 evidence?</p> <p>14 A. Yes, but then it goes down a hierarchy,</p> <p>15 because in terms of the FDA's definition, they can</p> <p>16 go down to like case studies and stuff, so --</p> <p>17 Q. I'll read them to you. We'll kind of take</p> <p>18 it one at a time.</p> <p>19 Does valid -- valid scientific evidence may</p> <p>20 include a well-designed randomized clinical trial?</p> <p>21 A. Yes.</p> <p>22 Q. Valid scientific evidence may include</p> <p>23 partially controlled studies?</p> <p>24 A. Yes.</p> <p>25 Q. Valid scientific evidence may include</p>	<p style="text-align: right;">Page 164</p> <p>1 A. Valid -- because they can be used for</p> <p>2 safety. Any -- any patient and human experience can</p> <p>3 be used for safety.</p> <p>4 Q. Let me ask the question a different way.</p> <p>5 Would you agree that the FDA does not</p> <p>6 consider valid scientific evidence -- strike that.</p> <p>7 Would you agree that the FDA does not</p> <p>8 consider isolated case reports as valid scientific</p> <p>9 evidence to show safety or effectiveness?</p> <p>10 A. For effectiveness particularly, but they</p> <p>11 will consider them for safety. You get to decide.</p> <p>12 Q. Do you agree that the FDA does not consider</p> <p>13 random experience as valid scientific evidence to</p> <p>14 show safety or effectiveness?</p> <p>15 A. Effectiveness particularly, because</p> <p>16 remember, that's the key is what they clear things</p> <p>17 on or approve it on is effectiveness. So, yeah,</p> <p>18 that's not going to cut it for effectiveness, but</p> <p>19 safety it may.</p> <p>20 Q. Well, the FDA doesn't consider isolated case</p> <p>21 reports or random experience as valid scientific</p> <p>22 evidence to show safety.</p> <p>23 Would you agree or disagree with that?</p> <p>24 A. I disagree with that, because of postmarket</p> <p>25 surveillance. You have to use that information to</p>
<p style="text-align: right;">Page 163</p> <p>1 studies and objective trials without match controls?</p> <p>2 A. Yes.</p> <p>3 Q. And valid scientific evidence may include</p> <p>4 well-documented case histories conducted by</p> <p>5 qualified experts?</p> <p>6 A. Yes.</p> <p>7 Q. And valid scientific evidence may include</p> <p>8 reports of significant human experience with a</p> <p>9 marketed device from which it can fairly and</p> <p>10 responsibly be concluded that there's a reasonable</p> <p>11 assurance of safety and effectiveness of a device</p> <p>12 under its conditions of use; correct?</p> <p>13 MR. GAGE: Objection to form.</p> <p>14 THE WITNESS: Yes.</p> <p>15 MR. GAGE: Is that because I read it</p> <p>16 too quickly?</p> <p>17 MR. AYLSTOCK: I couldn't understand</p> <p>18 what that --</p> <p>19 MR. GAGE: She understands it because</p> <p>20 she knows it's a specific regulatory definition.</p> <p>21 THE WITNESS: Right.</p> <p>22 BY MR. GAGE:</p> <p>23 Q. Would you agree that the following are not</p> <p>24 considered valid scientific evidence to show safety</p> <p>25 or effectiveness: Isolated case reports?</p>	<p style="text-align: right;">Page 165</p> <p>1 come up with the postmarket information.</p> <p>2 Q. I think -- I think --</p> <p>3 A. You're not going to approve it or clear it</p> <p>4 on random case things, but you still consider the</p> <p>5 safety information.</p> <p>6 Q. I think that may be where we're missing, and</p> <p>7 I think when we talk about showing safety or</p> <p>8 effectiveness, we're talking about the definition</p> <p>9 under a 510(k).</p> <p>10 A. Yeah.</p> <p>11 But, remember, most things are showing</p> <p>12 effectiveness in terms of clearance and approval.</p> <p>13 Safety is harder to demonstrate.</p> <p>14 And so everything about a use of a product</p> <p>15 can relate to safety, and that's why your postmarket</p> <p>16 surveillance, obviously, you update your levels</p> <p>17 based on safety information from various sources,</p> <p>18 including it could be a case report, so -- so safety</p> <p>19 is a little different than efficacy.</p> <p>20 Q. Would you agree that the FDA does not</p> <p>21 consider unsubstantiated opinions to be valid</p> <p>22 scientific evidence to show safety and</p> <p>23 effectiveness?</p> <p>24 A. Yeah. Again, for clearance and approval.</p> <p>25 Q. Dr. Parisian, do you understand Prolift+M to</p>

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<p style="text-align: right;">Page 166</p> <p>1 have larger pores and less weight than Prolift?</p> <p>2 A. That's theoretically what it's supposed to</p> <p>3 be. It's GYNEMESH, but then they've put in the --</p> <p>4 the Monocryl, and so supposedly when the Monocryl is</p> <p>5 gone, you have a lighter weight mesh. It's supposed</p> <p>6 to be 20 to 30 grams some -- and so theoretically</p> <p>7 it's going to be lighter weight when that Monocryl</p> <p>8 has gone away.</p> <p>9 Q. Do you believe that Prolift+M is more safe</p> <p>10 or less safe than Prolift?</p> <p>11 MR. JONES: Objection.</p> <p>12 THE WITNESS: You know, I don't know.</p> <p>13 I don't have an opinion. I think -- I don't have</p> <p>14 any -- I mean, in terms of the 510(k), there was</p> <p>15 less data about Prolift+M than there was about</p> <p>16 Prolift, both of which seemed to have problems.</p> <p>17 Prolift definitely had problems, but</p> <p>18 that was what the FDA was saying. They didn't know</p> <p>19 that Prolift+M was more safe. I mean, there's no</p> <p>20 data to support it.</p> <p>21 MR. AYLSTOCK: I think we're done.</p> <p>22 MR. GAGE: Yeah, we're done.</p> <p>23 Well, we're done because my time is up.</p> <p>24 (Concluded at 12:27 p.m., and then</p> <p>25 re-opened at 2:05 p.m.)</p>	<p style="text-align: right;">Page 168</p> <p>1 A. No. That can be in there.</p> <p>2 Q. I'm sorry?</p> <p>3 A. That's PROLENE, so that's okay.</p> <p>4 Q. So do you want -- okay. So I've got some</p> <p>5 patent and trademark information about PROLENE?</p> <p>6 A. Right.</p> <p>7 Q. I've got some stuff about Textile</p> <p>8 Development Associates. It's called polypropylene</p> <p>9 monofilament knitted mesh fabrics, a United States</p> <p>10 Patent, and then an ORDV 510(k) sterility review</p> <p>11 guidance?</p> <p>12 A. Correct.</p> <p>13 Q. Are these documents pertinent to your</p> <p>14 opinions on Prolift+M or just TVT-Secur or to both?</p> <p>15 A. The TVT-Secur, yes. The sterility guidance,</p> <p>16 I don't think that really is an issue that we're</p> <p>17 talking about, so it just is in there. It's just</p> <p>18 one page, but -- and then the other document there</p> <p>19 that I gave you is for the Dura Patch.</p> <p>20 Q. All right. And why don't we do it like</p> <p>21 this. Let me ask you -- and I'm going to -- since</p> <p>22 we only have one copy, I'm going to kind of come</p> <p>23 around and hover over you if you don't mind.</p> <p>24 A. No problem.</p> <p>25 Q. On Exhibit -- Parisian Exhibit No. 9 to your</p>
<p style="text-align: right;">Page 167</p> <p>1 (Whereupon, Exhibit No. 19 was marked</p> <p>2 for identification.)</p> <p>3 BY MR. GAGE:</p> <p>4 Q. All right. Dr. Parisian, counsel have all</p> <p>5 agreed to reopen the record on our concluded</p> <p>6 Prolift+M deposition so that we could cover a</p> <p>7 document that you forgot to bring to my attention</p> <p>8 earlier this morning that's pertinent to Prolift+M.</p> <p>9 I'm handing you a document that -- or a</p> <p>10 collection of documents, actually, that I have</p> <p>11 marked collectively as Parisian Exhibit No. 19 to</p> <p>12 your Prolift+M deposition.</p> <p>13 Could you tell me what those are?</p> <p>14 A. Yes. And I thought I had given them to you</p> <p>15 this morning, but I hadn't.</p> <p>16 It's the medical literatures, some of my</p> <p>17 searches that I have in my file for Prolift+M and</p> <p>18 about risk -- the French studies particularly.</p> <p>19 And the reason I got confused is because</p> <p>20 the -- let me just take one document out of here</p> <p>21 because --</p> <p>22 Q. And, Dr. Parisian, before you finish, are</p> <p>23 there other documents in my hand that need to be</p> <p>24 made part of that composite exhibit, because I've</p> <p>25 got a US Patent for knitted surgical mesh?</p>	<p style="text-align: right;">Page 169</p> <p>1 Prolift+M deposition, it looks to be a French study</p> <p>2 with some of your -- with some handwriting on it?</p> <p>3 A. Right. It's my handwriting, my</p> <p>4 highlighting.</p> <p>5 Q. All right. And you reference several times</p> <p>6 during your deposition a French study?</p> <p>7 A. Yes, sir. And that's the French study.</p> <p>8 Q. And this document purports to be the French</p> <p>9 study that you were referencing as you were</p> <p>10 testifying earlier this morning?</p> <p>11 A. It is related to it. I went and got -- this</p> <p>12 is 2007, yes, but this is one of the French studies</p> <p>13 that I went and looked at.</p> <p>14 Q. All right. Now, there's another document in</p> <p>15 this collection that's an abstract called</p> <p>16 "Mesh-related infections after pelvic organ prolapse</p> <p>17 repair surgery"?</p> <p>18 A. Yes, sir.</p> <p>19 Q. And what was the significance, if any, of</p> <p>20 this document to your Prolift+M opinions?</p> <p>21 A. I was looking at the time, and it was about</p> <p>22 infection, and I didn't see that it was one of the</p> <p>23 ones that was in reference to the FDA. And it was</p> <p>24 an article about infection in vaginal meshes, so it</p> <p>25 was just basically looking at what information was</p>

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<p style="text-align: right;">Page 170</p> <p>1 available at that time.</p> <p>2 Q. All right. And that's an abstract study,</p> <p>3 2007?</p> <p>4 A. 2007.</p> <p>5 Q. And then -- all right. Let me just back up</p> <p>6 real quick.</p> <p>7 For the French study and the 2007 abstract,</p> <p>8 are those documents that were provided to you by</p> <p>9 counsel, or are those documents that you got on your</p> <p>10 own research?</p> <p>11 A. Oh, I got them. They're mine. This comes</p> <p>12 off the Ethicon Web site, and it's the -- it's the</p> <p>13 reference list for a physician, and so I went</p> <p>14 through the reference list looking to see, this</p> <p>15 would be information for a physician.</p> <p>16 I guess I downloaded it -- when did I</p> <p>17 download it? December 2015. And I've highlighted</p> <p>18 the ones that were specifically due to vaginal mesh</p> <p>19 in this thing.</p> <p>20 There's like 256 references, and there's</p> <p>21 only a few that are anything to do with vaginal</p> <p>22 mesh. Most of them were hernia.</p> <p>23 You have that.</p> <p>24 Q. All right. So the record is clear,</p> <p>25 Dr. Parisian, what we're talking about is a document</p>	<p style="text-align: right;">Page 172</p> <p>1 Q. And these are my words, not yours, so</p> <p>2 correct me if I mistake.</p> <p>3 But am I understanding this to be an omnibus</p> <p>4 listing of medical references that would pertain to</p> <p>5 the entirety of the Ethicon product line?</p> <p>6 A. Yes.</p> <p>7 Q. All right. And your purpose for going</p> <p>8 through that was simply to determine how many</p> <p>9 pertain to mesh and how many pertain to non-mesh</p> <p>10 devices by Ethicon?</p> <p>11 A. That wasn't my reason. My reason was just</p> <p>12 that I was looking at the reference list to see what</p> <p>13 was in it. And then when I started looking at it, I</p> <p>14 went, gosh, there aren't many, and so I went through</p> <p>15 and I picked out the ones that were vaginal mesh.</p> <p>16 Q. Are these -- what is a manufacturer supposed</p> <p>17 to do with regard to reference lists on a Web site?</p> <p>18 Is there some -- is there a standard or a regulatory</p> <p>19 expectation?</p> <p>20 A. Well, you give them fair balance. Most of</p> <p>21 those articles are very positive, so if physicians</p> <p>22 went to their Web site and wanted to find out risk</p> <p>23 information, there's not risk information. Most of</p> <p>24 these are benefits. So it's not balanced in terms</p> <p>25 of giving a physician -- because like you were</p>
<p style="text-align: right;">Page 171</p> <p>1 that is within the collection of Exhibit No. 19, the</p> <p>2 first page of which is -- says at the top,</p> <p>3 "References Ethicon page 3 of 13"; correct?</p> <p>4 A. Right.</p> <p>5 And so if you go on the Ethicon Web site and</p> <p>6 you hit physician and then you hit references, this</p> <p>7 is the printout of 459 studies or references on the</p> <p>8 Ethicon Web site. And so it's for everything.</p> <p>9 And so I went and looked to see how many of</p> <p>10 their 459 had anything to do with vaginal mesh, and</p> <p>11 23 of them did, and that would be about roughly</p> <p>12 5 percent.</p> <p>13 Q. Okay.</p> <p>14 A. So a physician if you went here, there's not</p> <p>15 a lot about vaginal mesh. It's mainly about</p> <p>16 bariatric surgery, hernia, but not much about mesh.</p> <p>17 Q. And you did this review on</p> <p>18 December 16, 2015 --</p> <p>19 A. Yes, sir.</p> <p>20 Q. -- as evidenced by the date in the bottom</p> <p>21 right-hand corner?</p> <p>22 A. Yes, sir.</p> <p>23 Q. And do you understand this list to pertain</p> <p>24 to all products sold by Ethicon?</p> <p>25 A. Yes, sir.</p>	<p style="text-align: right;">Page 173</p> <p>1 saying, physicians should go look up surgical mesh.</p> <p>2 Q. Yes.</p> <p>3 A. If you go to the Ethicon Web site, there's</p> <p>4 not a lot about risk. There's a lot about benefits.</p> <p>5 Most of these studies are benefits. The Nielson</p> <p>6 studies and here it is, Nielson 11 year, so if you</p> <p>7 were a surgeon, you're going to say, oh, look. It's</p> <p>8 pretty good. All this stuff is good stuff.</p> <p>9 And so it's not -- in terms of fair balance,</p> <p>10 it's not giving you the risk information.</p> <p>11 Q. All right. So if we go -- if we continue</p> <p>12 further in this document which is marked as</p> <p>13 collective Exhibit 19, I find another abstract, for</p> <p>14 lack of better pronunciation, Collinet,</p> <p>15 C-o-l-l-i-n-e-t --</p> <p>16 A. Um-hmm.</p> <p>17 Q. -- on Column A, article. Is that correct?</p> <p>18 A. Um-hmm. Yes, sir.</p> <p>19 Q. And the handwriting and the highlighting is</p> <p>20 yours?</p> <p>21 A. Yes, sir.</p> <p>22 So this is another French -- and so these</p> <p>23 are -- they're talking about risk factors, and this</p> <p>24 is a French article. That's why I'm looking at the</p> <p>25 abstract.</p>

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<p style="text-align: right;">Page 174</p> <p>1 But risk factors not referenced for the FDA, 2 and then they're talking about the numbers that I 3 have, 12.27 mesh exposures in two months, so I'm 4 getting the information from this article, and that 5 information was available in 2006 before the FDA 6 even looked at the 510(k). And that information is 7 not in there. 8 Q. Well, let me ask you this: Is this for 9 Prolift+M or is this for Prolift? 10 A. This is for Prolift. Yeah, this is for 11 Prolift because it was being done in France. 12 Q. Should the -- should the -- should Ethicon 13 provide the FDA in its Prolift -- Prolift+M 510(k) 14 the medical literature for Prolift? 15 MR. JONES: Objection. Are we -- are 16 we -- I feel like we're getting into rehashing 17 Prolift+M issues and not just marking an exhibit and 18 asking her what she marked. 19 You're kind of getting into asking 20 her -- to me, you're asking her now about 21 substantive opinions outside of this exhibit that 22 you're -- that we marked. 23 MR. GAGE: I mean, I know, but I mean, 24 I didn't have the exhibit. 25 MR. JONES: I mean, you get what I'm</p>	<p style="text-align: right;">Page 176</p> <p>1 A. That's right. 2 Q. Okay. Did the -- okay. So here the next 3 one says -- it's another abstract. It says, "Risk 4 factors for prosthesis exposure in treatment of 5 genital prolapse via the vaginal approach"? 6 A. Right. 7 Q. And you've got written on here, "Earlier -- 8 not given." Is that correct? 9 A. That's correct. 10 Q. And this is an abstract authored by Belot, 11 B-e-l-o-t; correct? 12 A. Right. And so this is more information that 13 they would have had that they didn't provide to the 14 FDA in their 510(k). 15 Q. Okay. Is the Collinet and the Belot 16 abstracts, are those listed in that list of 17 literature on the Ethicon Web site, or did you find 18 those through like a PubMed search? 19 A. Oh, I did this on a PubMed search. They're 20 not on the FDA's website. I mean, they're not on 21 Ethicon's Web site, no. These are ones I found. 22 Q. Does FDA do PubMed searches when they get 23 510(k) applications? 24 A. No, no, because it's up to the manufacturer 25 to do them; not the FDA. FDA had -- particularly at</p>
<p style="text-align: right;">Page 175</p> <p>1 getting at? 2 Are you getting close? 3 MR. GAGE: It's a quick Q and A. 4 THE WITNESS: My quick answer is yes, 5 they should have because it is a Prolift, Prolift+M 6 510(k). And this was the history of what they're 7 proposing to the FDA, so, yes, they should have. 8 BY MR. GAGE: 9 Q. Okay. Let me ask you this: If the 510(k)s 10 had been separate, would you have expected Ethicon 11 to submit with the Prolift+M 510(k) literature 12 pertinent to Prolift? 13 A. Yeah -- 14 MR. JONES: Objection. 15 THE WITNESS: -- because it's actually 16 the predicate. They originally made it so that 17 Prolift was the predicate. Well, this is -- the 18 Prolift predicate has got this significant failure 19 issue, so the FDA needs to know, are we making 20 changes to Prolift+M because we're addressing the 21 safety issues. 22 BY MR. GAGE: 23 Q. Okay. And when you say "failure," you're 24 talking about the mesh exposure rate reported in 25 this study?</p>	<p style="text-align: right;">Page 177</p> <p>1 this period of time, they didn't really have access 2 to the NIH. 3 If you look at that document in 2007 I had 4 for the FDA, they actually talk about having people 5 go get them articles from the library because 6 there's a library at FDA. So they -- those 7 reviewers don't do their own searches as a rule. 8 They have somebody else that you have to go through 9 to get stuff. 10 Q. Is that still the rule today? 11 A. I don't know. I mean, I don't know. I 12 was -- but you can't -- it's not up to the FDA to go 13 get the literature. 14 Q. Do you know what -- all right. So let's 15 look at these documents. 16 This one was the -- what did you call it, 17 the Dura -- 18 A. The Dura Patch. 19 Q. Dura Patch? 20 A. This is a neurological patch here. 21 Q. All right. 22 MR. GAGE: So let me mark this as -- 23 (Discussion off the record.) 24 BY MR. GAGE: 25 Q. All right. So have we now covered the</p>

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additional documents that you found and after we had concluded the Prolift+M deposition?

A. Yes, sir.

Q. Okay. So the documents that you handed me and marked to me, were those documents that you had at the time you wrote your Prolift+M deposition [sic], or were those documents that you got after you wrote your Prolift+M -- strike that.

With regard to Exhibit 19, were these documents that you had in your possession before you wrote your Prolift+M report or after you wrote it?

A. Before.

Q. Okay. All right.

MR. GAGE: Now I believe we can conclude the Prolift+M deposition and go back into the TVT-Secur deposition.

(Deposition concluded at 2:18 p.m.)

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CERTIFICATE

I, ALISA SMITH, Registered Professional Reporter, Arizona Certified Reporter, do hereby certify that, pursuant to notice, the deposition of SUZANNE PARISIAN, M.D. was duly taken on March 8, 2016, at 9:06 a.m. before me.

The said SUZANNE PARISIAN, M.D. was duly sworn by me according to law to tell the truth, the whole truth, and nothing but the truth and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me.

I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

Alisa Smith, RPR, AZ CR 50712

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I, SUZANNE PARISIAN, M.D., do hereby
 acknowledge that I have read the foregoing pages, 5
 through 178, and that the same is a correct
 transcription of the answers given by me to the
 questions therein propounded, except for the
 corrections or changes in form or substance, if any,
 noted in the attached Errata Sheet.

 SUZANNE PARISIAN, M.D.

 DATE

Subscribed and sworn to before me this

____ day of _____, 20____.

My Commission expires: _____

 Notary Public

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LAWYER'S NOTES

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